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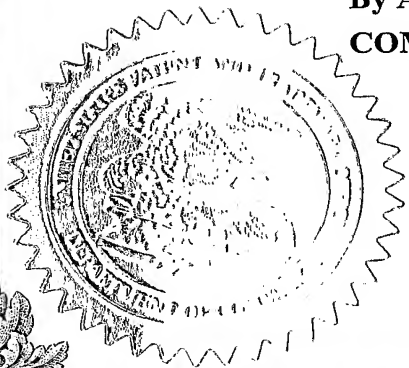
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LANAI JAMISON  
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# Mail Stop Provisional Patent Application

PTO/SB/16 (6-95)

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## PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53 (c).

Docket Number		4398-319	Type a plus sign (+) inside this box →	+
INVENTOR(S)/APPLICANT(S)				
LAST NAME	FIRST NAME	MIDDLE INITIAL	RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)	
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TITLE OF THE INVENTION (280 characters)				
HEADGEAR CONNECTION ASSEMBLY FOR A RESPIRATORY MASK ASSEMBLY				
CORRESPONDENCE ADDRESS				
Direct all correspondence to:				
<input checked="" type="checkbox"/> Customer Number:		23117		Place Customer Number Bar Label Here →
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ENCLOSED APPLICATION PARTS (check all that apply)				
<input checked="" type="checkbox"/> Specification	Number of Pages	22	<input type="checkbox"/> Applicant claims "small entity" status.	
<input checked="" type="checkbox"/> Drawing(s)	Number of Sheets	27	<input type="checkbox"/> "Small entity" statement attached.	
		<input type="checkbox"/> Other (specify) _____		
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<input checked="" type="checkbox"/> A check or money order is enclosed to cover the Provisional filing fees (\$160.00)/(\$80.00)			PROVISIONAL FILING FEE AMOUNT (\$)	160.00
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.				

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.



No.



Yes, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,  
SIGNATURE

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January 16, 2004

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REGISTRATION NO.  
(if appropriate)

38,009



Additional inventors are being named on separately numbered sheets attached hereto.

## PROVISIONAL APPLICATION FILING ONLY

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# ***U.S. PATENT APPLICATION***

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***Invention:*** HEADGEAR CONNECTION ASSEMBLY FOR A RESPIRATORY MASK  
ASSEMBLY

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## ***SPECIFICATION***

## **HEADGEAR CONNECTION ASSEMBLY FOR A RESPIRATORY MASK ASSEMBLY**

### **CROSS-REFERENCE TO APPLICATIONS**

**[0001]** Each of the following applications is hereby incorporated herein by reference in its entirety: U.S. Non-Provisional Patent Application Serial No. 10/655,603 filed September 5, 2003; U.S. Provisional Application Serial No. 60/424,698 filed November 8, 2002; U.S. Provisional Application Serial No. 60/467,571 filed May 5, 2003; and U.S. Non-Provisional Application Serial No. 10/235,846 filed September 6, 2002, which claims priority to U.S. Provisional Application No. 60/317,486 filed September 7, 2001 and U.S. Provisional Application Serial No. 60/342,854 filed December 28, 2001.

### **FIELD OF THE INVENTION**

**[0002]** The present invention relates to a headgear connection assembly for use in removably attaching a headgear assembly to a frame of a respiratory mask assembly, the mask assembly being used for treatment, e.g., of Sleep Disordered Breathing (SDB) with Non-invasive Positive Pressure Ventilation (NPPV).

### **BACKGROUND OF THE INVENTION**

**[0003]** Respiratory mask assemblies used in the treatment of SDB may comprise a nasal mask designed to fit over a patient's nose, or a full face mask designed to fit over the nose and mouth of the patient. Air or other breathable gas is supplied by a blower and passed along a flexible conduit to the mask assembly.

**[0004]** The mask assembly generally comprises a relatively rigid shell, e.g., a frame, which defines a rearwardly opening cavity covering the patient's nose and/or mouth, and a soft portion, e.g., a cushion, which spaces the frame away from the face of the patient for comfortable contact.

**[0005]** The mask assembly is usually held in place using a headgear assembly, the frame and headgear assembly being joined using some form of connector.

**[0006]** One form of known connector is described in U.S. Patent No. 6,374,826 (Gunaratnam et al.). The contents of this patent are hereby incorporated by reference.

**[0007]** Some patients have poor dexterity, and hence find certain arrangements of connectors awkward or difficult to use. For example, some patients may have difficulty in

correctly joining the frame and headgear assembly with the connector. As a result, the connector may disengage during use or may become stuck so it becomes difficult for the patient to disconnect the frame from the headgear assembly.

**[0008]** Furthermore, some connectors are positioned on the frame of the mask assembly which makes it difficult for the user to see the connectors, because they are very close to the eyes or out of the range of vision of the patient. Hence, it is important to have a connector which is easy to use and which is easy to correctly assemble even if it is out of the range of vision of the patient.

#### SUMMARY OF THE INVENTION

**[0009]** One aspect of the present invention is to provide a respiratory mask assembly having a headgear connection assembly positioned between the frame and headgear assembly in a convenient and intuitive location for quick attachment and/or detachment by the patient, while not being easily detached accidentally.

**[0010]** Another aspect of the present invention provides a respiratory mask assembly for delivering breathable gas to a patient. The respiratory mask assembly according to one embodiment includes a frame and at least one locking clip. The frame has a main body and a side frame member provided on each lateral side of the main body. At least one of the side frame members includes an integrally formed locking clip receiver assembly. The at least one locking clip has a main body providing a front portion and a rear portion. The front portion is adapted to be removably coupled with the at least one locking clip receiver assembly and the rear portion is adapted to be removably coupled to a headgear assembly. The rear portion of the locking clip includes a cross bar that forms an opening through which a strap of the headgear assembly can pass and be removably coupled with the cross bar, and the front portion of the locking clip includes at least one resiliently flexible spring arm that is flexible within the plane of the main body.

**[0011]** Another aspect of the invention is to provide a headgear connection assembly which can be easily molded in a mask frame which includes a swivel elbow connector.

**[0012]** Another aspect of the invention is to provide a locking clip that includes a flexing spring arm having a length that is effectively increased while maintaining a compact size, without sacrificing spring/clip retention forces.

[0013] Other aspects, features and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

[0015] Fig. 1 is a front perspective view illustrating a mask assembly having a headgear connection assembly constructed in accordance with an embodiment of the invention;

[0016] Fig. 2 is a front view of the mask assembly showing Fig. 1;

[0017] Fig. 3 is a top view of a locking clip of the headgear connection assembly shown in Fig. 1;

[0018] Fig. 4 is a perspective view of a locking clip of the headgear connection assembly shown in Fig. 1;

[0019] Fig. 5 is a perspective view of a locking clip receiver assembly of the headgear connection assembly shown in Fig. 1;

[0020] Fig. 6 is a front view of a locking clip receiver assembly of the headgear connection assembly shown in Fig. 1;

[0021] Fig. 7 is a cross-sectional view of a locking clip receiver assembly of the headgear connection assembly shown in Fig. 1;

[0022] Fig. 8 is a cross-sectional view illustrating the engagement between a locking clip and a locking clip receiver assembly of the headgear connection assembly shown in Fig. 1;

[0023] Fig. 9 is a cross-sectional view illustrating the engagement between a locking clip and a locking clip receiver assembly of the headgear connection assembly shown in Fig. 1;

[0024] Fig. 10 is a perspective view illustrating the mask assembly of Fig. 1 being secured to a patient's face by a headgear connection assembly of Fig. 1;

[0025] Fig. 11 is a top view illustrating the headgear connection assembly of Fig. 1 in a first incorrect position with respect to the frame of the mask assembly;

[0026] Fig. 12 is a top view illustrating the headgear connection assembly of Fig. 1 in a second incorrect position with respect to the frame of the mask assembly;

[0027] Fig. 13 is a front perspective view of a locking clip of the headgear connection assembly shown in Fig. 1;

[0028] Fig. 14 is a rear perspective view of the locking clip shown in Fig. 13;

[0029] Fig. 15 is a top view of the locking clip shown in Fig. 13;

[0030] Fig. 16 is a cross-section taken along line 16-16 of Fig. 15;

[0031] Fig. 17 is a front view of the locking clip shown in Fig. 13;

[0032] Fig. 18 is a rear view of the locking clip shown in Fig. 13;

[0033] Fig. 19 is a side view of the locking clip shown in Fig. 13;

[0034] Fig. 20 is a bottom view of the locking clip shown in Fig. 13;

[0035] Fig. 21 is a front perspective view of another embodiment of a locking clip;

[0036] Fig. 22 is a rear perspective view of the locking clip shown in Fig. 21;

[0037] Fig. 23 is a top view of the locking clip shown in Fig. 21;

[0038] Fig. 24 is a cross-section taken along line 24-24 of Fig. 23;

[0039] Fig. 25 is a front view of the locking clip shown in Fig. 21;

[0040] Fig. 26 is a rear view of the locking clip shown in Fig. 21;

[0041] Fig. 27 is a side view of the locking clip shown in Fig. 21;

[0042] Fig. 28 is a bottom view of the locking clip shown in Fig. 21;

[0043] Fig. 29 is a front perspective view illustrating an embodiment of a frame for a full-face mask assembly, the frame having a locking clip receiver assembly structured to interlock with the locking clip shown in Fig. 21;

[0044] Fig. 30 is a front perspective view, similar to Fig. 29 but at a different angle, of the frame shown in Fig. 29;

[0045] Fig. 31 is a rear perspective view of the frame shown in Fig. 29;

[0046] Fig. 32 is a front view of the frame shown in Fig. 29;

[0047] Fig. 33 is a side view of the frame shown in Fig. 29;

[0048] Fig. 34 is a top view of the frame shown in Fig. 29;

[0049] Fig. 35 is a top perspective view illustrating an embodiment of a forehead support adapted to be movably mounted to an upper portion of the frame shown in Fig. 29, the forehead support having a locking clip receiver assembly structured to interlock with the locking clip shown in Fig. 21;

[0050] Fig. 36 is a rear perspective view of the forehead support shown in Fig. 35;



- [0051] Fig. 37 is a front perspective view of the forehead support shown in Fig. 35;
- [0052] Fig. 38 is a front view of the forehead support shown in Fig. 35;
- [0053] Fig. 39 is a side view of the forehead support shown in Fig. 35;
- [0054] Fig. 40 is a top view of the forehead support shown in Fig. 35;
- [0055] Fig. 41 is a front view of a locking clip according to another embodiment of the present invention;
- [0056] Fig. 42 is a rear view thereof;
- [0057] Fig. 43 is a front perspective view thereof;
- [0058] Fig. 44 is a front view of a locking clip according to another embodiment of the present invention;
- [0059] Fig. 45 is a rear view thereof;
- [0060] Fig. 46 is a front perspective view thereof;
- [0061] Fig. 47 is a front view of a locking clip according to another embodiment of the present invention;
- [0062] Fig. 48 is a rear view thereof;
- [0063] Fig. 49 is a front perspective view thereof; and
- [0064] Fig. 50 is a side view thereof.

#### DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0065] Figs. 1 and 2 shown a respiratory mask assembly 10 that includes a frame 12 and a cushion 14 that may be permanently or removably connected to the frame 12. For example, the cushion 14 may be removably attached to the frame 12 with a cushion clip, straps, a friction or interference fit, and/or a tongue-in-groove arrangement, as is known in the art. However, the cushion 14 may be permanently attached to the frame 12 with glue and/or mechanical fastening means, for example.

[0066] A forehead support 16 is movably mounted to an upper portion of the frame 12. A headgear assembly (not shown) can be removably attached to the frame 12 to maintain the frame 12 and cushion 14 in a desired adjusted position on the patient's face. For example, the headgear assembly may include a pair of upper and lower straps with the upper straps removably connected to clip structures 18 provided on the forehead support 16 and the lower straps removably connected the frame 12 by a headgear connection assembly 20, as will be further discussed below.

[0067] In the illustrated embodiment, the mask assembly 10 is a nasal mask structure to deliver breathable gas to a patient's nose. However, the mask assembly 10 may be a nasal and mouth mask, or the mask assembly may be a full face mask.

[0068] A swivel elbow assembly 22 is removably attached to a front portion of the frame 12. The elbow assembly 22 is structured to be connected to a conduit that is connected to a pressurized supply. The pressurized supply supplies pressurized breathable gas through the conduit and elbow assembly 22 and into the cushion 14 for breathing by the patient.

[0069] In the illustrated embodiment, lower straps of the headgear assembly are removably attached to the frame 12 by a headgear connection assembly 20. The headgear connection assembly 20 includes a first connector portion 24 provided by the frame 12 and a second connector portion 26 adapted to be removably coupled with the first connector portion 24. The second connector portion 26 is removably connected to the lower straps of the headgear assembly.

[0070] As shown in Figs. 1-2, the second connector portion 26 includes a pair of locking clips 28. In a preferred embodiment, the locking clip 28 is a unitary plastic piece formed by injection molding. As shown in Figs. 3 and 4, each locking clip 28 includes a main body 30 having a rear portion 32 and a front portion 34. The rear portion 32 is removably connected to a lower strap of the headgear assembly and the front portion 34 is removably coupled with the first connector portion 24 provided on the frame 12.

[0071] Specifically, the front portion 34 includes at least one and preferably two resiliently flexible spring arms 36 that are attached to opposite sides of the main body 30 and extend away from the main body 30 in a generally parallel manner. However, the front portion 34 may include one spring arm 36. The spring arms 36 can flex up and down, e.g., in the direction of arrows A or in a reverse direction of arrows A, respectively, as shown in Fig. 3. A locking tab 38 is attached to a free end of each spring arm 36. Further, each spring arm 36 is configured to provide a shoulder portion 40. In use, the shoulder portions 40 and locking tabs 38 are adapted to engage with corresponding portions of the first connector portion 24 for coupling the first and second connector portions 24, 26 with one another. For example, the locking tabs 38 are structured to prevent accidental disengagement of the second connector portion 26 from the first connector portion 24 if a force is applied to the second connector portion 26 in the direction of arrow B (Fig. 3), as will be further discussed.

[0072] The front portion 32 also includes a central support tab 42 positioned between the pair of spring arms 36. In the illustrated embodiment, the central support tab 42

has a length that is greater than the length of each of the spring arms 36. The central support tab 42 is slidably insertable into a complimentary shaped portion of the first connector portion 24, as will be further discussed.

**[0073]** As shown in Fig. 4, the central support tab 42 includes a groove 44. The central support tab 42 has a height of  $h_2$ , and the front portion of each spring arm 36 has a height of  $h_1$ . In the illustrated embodiment, the height  $h_2$  is larger than the height  $h_1$ . In an alternative embodiment,  $h_2$  may be smaller than  $h_1$ .

**[0074]** The rear portion 32 of the second connector portion 26 includes a cross bar 46 that forms an opening 48 through which a lower strap of the headgear assembly may pass and be removably connected. Specifically, an end portion of the lower strap of the headgear assembly may be wrapped around the cross bar 46. Fastening of the lower strap to the cross bar 46 may be assisted by use of a hook and loop material, such as Velcro®. Thus, the lower strap may be adjusted with respect to the locking clip 28 for proper fit. The locking clip 28 may be rotatably adjustable with respect to the headgear assembly, e.g., see U.S. Provisional Application No. 60/402,509, filed on August, 12, 2002, incorporated herein by reference in its entirety.

**[0075]** As shown in Figs. 1, 2, and 5, the frame 12 includes a main body 50 accommodating the cushion 14 and a side frame member 52 provided on each lateral side of the main body 50. Each side frame member 52 includes the first connector portion 24 which is integrally formed therewith. As shown in Figs. 5-7, the first connector portion 24 includes a locking clip receiver assembly 54. The locking clip 28 is structured to interlock with the locking clip receiver assembly 54 to removably attach the locking clip 28, and hence the headgear assembly, to the frame 12.

**[0076]** Each locking clip receiver assembly 54 includes a slot 56 having a central portion 58 and two locking portions 60 positioned on opposite sides of the central portion 58. The central portion 58 of the slot 56 has an upper surface 62 that is continuous with an upper surface 64 of each of the locking portions 60. However, lower surfaces 66, 68 of the central portion 58 and two locking portions 60, respectively, have a stepped configuration. Specifically, as shown in Figs. 5 and 6, the central portion 58 has a height  $h_2$  between the upper surface 62 and lower surface 66 thereof. The two locking portions 60 have a height  $h_1$  between the upper surface 64 and lower surface 68 thereof. In the illustrated embodiment, the height  $h_2$  is greater than the height  $h_1$ . Moreover, the height  $h_2$  of the central portion 58 is approximately equal to the height  $h_2$  of the central support tab 42 and the height  $h_1$  of the two

locking portions 60 is approximately equal to the height  $h_1$  of the front portion of each spring arm 36. This arrangement facilitates the connection between the locking clip 28 and the locking clip receiver assembly 54, as will be further discussed.

[0077] As shown in Fig. 7, each of the locking portions 60 includes a locking flange 70 positioned on an outer wall thereof for engagement with the locking tab 38 of a locking clip 28.

[0078] The central portion 58 includes a wall 72 that extends upwardly from the lower surface 66 towards the upper surface 62. In the illustrated embodiment, the wall 72 extends approximately half the way to the upper surface 62.

[0079] In the illustrated embodiment, the first connector portions 24 are integrally molded with the frame 12. As shown in Figs. 5 and 10, the frame 12 also includes an orifice 80 and collar 82 adapted to receive a swivel elbow 22 (Figs. 1 and 2). The collar 82 has a rim 84 which extends horizontally and radially from the orifice 80. In order to form the collar 82, it is advantageous if the mold can be withdrawn horizontally. However, it is desirable that the headgear be presented at an angle with respect to the frame 12. The first connector portions 24 are aligned downwardly at an angle  $\theta$  of approximately 5% with respect to the horizontal. When the frame 12 is molded, the mold components should be withdrawn in a horizontal direction to form the collar 82. As shown in Fig. 7, the junction between the lower surfaces 66, 68 of the central portion 58 and locking portions 60, respectively, is arranged to make an angle  $\alpha$  which is sufficiently wide to enable the sides of the mold to be withdrawn in a horizontal direction. Further, the angled junction facilitates the connection between the locking clip 28 and the locking clip receiver assembly 54.

[0080] As shown in Fig. 9, the front portion 34 and rear portion 32 of the locking clip 28 are disposed at an angle  $\beta$  with respect to one another. In the illustrated embodiment, the rear portion 34 is angled downwardly with respect to the horizontal, whereas the front portion 32 is generally horizontally aligned. By use of this angle, the locking clip 28 does not protrude as far from the mask as it would otherwise. Furthermore, the headgear straps are connected to the locking clip 28 at an angle which more naturally follows the contour of the face. In an alternative form of the invention, the front and rear portions 34, 32 may be curved to achieve an angular difference between the front and rear. An advantage of either approach is that the slot 56 of the first connector portion 24 into which the front portion 34 of the second connector 26 is slidably received may be generally horizontal. This is advantageous during the

manufacture process because it means the sides of the mold may be withdrawn horizontally to assist formation of the collar 82.

**[0081]** As shown in Figs. 8-9, the locking portions 60 of the slot 56 are adapted to receive a respective one of the pair of spring arms 36, the locking tab 38 of each spring arm 36 interlocking with the locking flange 70 provided in respective locking portions 60 to removably attach the locking clip 28, and hence the headgear assembly, to the frame 12. The shoulder portion 40 of each locking clip 28 engages an engagement face 74 provided on the frame 12 when the locking clip 28 is inserted into the locking clip receiver assembly 54 to provide additional support for the locking clip 28. The locking tab 38 may interlock with an undercut provided in the locking portions 60 to removably attach the locking clip 28 to the frame 12. Further, each locking tab 38 may extend through a slot provided in the outer wall of the locking portion 60. The slot need not extend through the outer wall of the locking portion 60.

**[0082]** The central support tab 42 is inserted into the central portion 58 of the slot 56 when the locking clip 28 and locking clip receiver assembly 54 are engaged so as to prevent relative movement between the locking clip 28 and the locking clip receiver assembly 54.

**[0083]** Specifically, when the locking clip 28 is inserted into the locking clip receiver assembly 54, the spring arms 36 are forced toward one another (in the direction of arrows A as shown in Fig. 3) as the locking tabs 38 are inserted into respective locking portions 60 of the slot 56 and ride up and over the locking flanges 70. Once the locking tabs 38 have cleared respective locking flanges 70, the spring arms 36 can spring outwardly (in the reverse direction of arrows A as shown in Fig. 3) to provide a locking engagement between the locking tabs 38 and the locking flanges 70. Sufficient clearance is provided in the locking portions 60 of the slot 56 to allow the necessary movement of the locking tabs 38 to clear the locking flanges 70.

**[0084]** The central support tab 42 is configured to have a close fit with the central portion 58 of the slot 56 so that when the central support tab 42 is inserted into the central portion 58, little rotational, rocking or side-to-side movement is permitted between the locking clip 28 and the locking clip receiver assembly 54. The central support tab 42 is longer than the spring arms 36 to assist with alignment into the slot 56. Further, the groove 44 of the central support tab 42 engages the wall 72 provided in the central portion 58 of the slot 56 to facilitate entry of the central support tab 42 into the central portion 58 of the slot 56. Alternatively, the central support tab 42 may have a protrusion that engages a groove provided in the central

portion 58 of the slot 56. Also, the central support tab 42 has a shape that is complementary to the angle  $\alpha$  that defines the shape of the central portion 58 of the slot 56.

[0085] Because the height h2 of the central portion 58 is approximately equal to the height h2 of the central support tab 42 and the height h1 of the two locking portions 60 is approximately equal to the height h1 of the front portion of each spring arm 36, the locking portions 60 of the slot 56 are of sufficient height to accommodate the front portion of each spring arm 36, but insufficient to accommodate the central support tab 42. That is, the central support tab 42 is too thick to fit into the locking portions 60 of the slot 56. Because of this arrangement, it will be clear to the patient whether or not the locking clip 28 has been correctly engaged with the locking clip receiver assembly 54. Thus, the patient cannot inadvertently partly assemble the locking clip 28 to the locking clip receiver assembly 54 in such a way that it will accidentally release. For example, Fig. 11 illustrates a first incorrect position of the locking clip 28 with respect to the locking clip receiver assembly 54 and Fig. 12 illustrates a second incorrect position of the locking clip 28 with respect to the locking clip receiver assembly 54. In both instances, the patient is unable to insert the thicker central support tab 42 into the thinner locking portion 60 of the slot 56.

[0086] To release the locking clip 28 from the locking clip receiver assembly 54, the patient simply forces the spring arms 36 towards one another to clear the locking tabs 38 from respective locking flanges 70. Then, the patient pulls the locking clip 28 outwardly away from the frame 12 to disengage the locking clip 28 from the locking clip receiver assembly 54.

[0087] As shown in Fig. 8, the locking tabs 38 and central support tab 42 have rounded or contoured edges to facilitate entry into the slot 56. Also, the outward surfaces of the locking clip 28 and the frame 12 preferably form a generally coextensive continuous surface, which is not interrupted when connected. Preferably, the locking clip 28 is as wide as the side frame members 52, which facilitates tactile location of the locking clip 28 by the patient.

[0088] The spring arms 36 are designed to flex within the plane of the locking clip main body 30, which further improves the ease by which the locking clips 28 are attached and detached. This positioning improves the ergonomics of flexing the spring arms up and down. As shown in Fig. 10, the patient's thumb and opposing finger can be used to readily locate and operate the locking clips 28. The outward surface of the spring arms 36 may include a series of protrusions 76 to facilitate gripping of the locking clip 28 by the patient (see Fig. 8).

Further, the locking clips 28 are connected to the straps of the headgear assembly so that length adjustment may be provided.

[0089] An advantage of the headgear connection assembly 20 is that one locking clip 28 can be used with the locking clip receiver assembly 54 provided on each side frame member 52, thereby reducing manufacturing costs and the need for inventory.

[0090] Figs. 13-20 show further structural details in various dimensions in one embodiment of the locking clip 28 of the headgear connection assembly 20. For example, the locking clip 28 has a length in the range of 20-40 mm, preferably 29 mm, a width in the range of 20-40 mm, preferably 27.8 mm, and a height in the range of 4-8 mm, preferably 6.7 mm. In an embodiment of the locking clip 28, the dimensions illustrated in Figs. 13-20 may vary  $\pm$  10%.

[0091] In the illustrated embodiment, the rear portion 32 of the locking clip 28 includes a cross-bar 46 that forms an opening 48 through which a strap of the headgear assembly can be removably coupled with the cross-bar 46. In other forms of the invention, the strap of the headgear assembly is connected using other mechanisms. For example, the strap may include a hook which engages with a corresponding hole in the locking clip. In another form, the strap is sewn in position and is not removable. In another form, the strap is removable, and held in position by a friction fit.

[0092] In the illustrated embodiment, a locking clip in accordance with the invention is used only on a mask frame adjacent a swivel elbow, in the region of the mouth; and straps for connection to a forehead support of the mask assembly are held in position only by hook & loop material. Thus two locking clips are used on one mask. In another embodiment of the invention, four locking clips are used, two as illustrated, and a further two being used as part of the forehead support.

[0093] Figs. 21-28 illustrate another embodiment of a locking clip, indicated as 228. As shown in Figs. 29-40, the locking clip 228 is structured for use with a full-face mask assembly having a frame 212 (see Figs. 29-34) and a forehead support 216 (see Figs. 35-40). Specifically, as shown in Figs. 29-34, the frame 212 has a pair of locking clip receiver assemblies 254 structured to interlock with a pair of locking clips 228. As shown in Figs. 35-40, the forehead support 216 has a pair of locking clip receiver assemblies 254 structured to interlock with a pair of locking clips 228. However, the locking clip 228 and locking clip receiver assemblies 254 illustrated may be structured for use with a nasal mask or a nasal and mouth mask, for example.

[0094] As shown in Figs. 21-28, the locking clip 228 is substantially similar to the locking clip 28 described above. In contrast, the length of the groove 244 provided in clip 228 is greater than the length of the groove 44 provided in clip 28, as will be further discussed. The remaining elements of the locking clip 228 are similar to the elements of the locking clip 28 and are indicated with similar reference numerals.

[0095] Similar to the previous embodiment, the locking clip 228 includes a main body 230 having a rear portion 232 and a front portion 234. The rear portion 232 is removably connected to a strap of the headgear assembly and the front portion 234 is removably coupled with a respective locking clip receiver assembly 254 provided on the frame 212 or forehead support 216. The front portion 234 includes two resiliently flexible spring arms 236 that are attached to opposite sides of the main body 230. The flexible spring arms 236 are flexible within the plane of the main body 230.

[0096] Further, each spring arm 236 includes a locking tab 238 and a shoulder portion 240 adapted to engage with a respective locking clip receiver assembly 254 provided on the frame 212 or forehead support 216. As best shown in Figs. 22 and 28, the front portion 234 also includes a central support tab 242 that includes a groove 244.

[0097] The groove 244 provided in clip 228 is deeper or more elongated than the groove 44 provided in clip 28 (as best shown in Figs. 14 and 22). In the illustrated embodiment, the groove 244 has a length that is at least half a length of the central support tab 242. The elongated groove in clip 228 facilitates with alignment of the clip 228 with the frame 212 or forehead support 216. Moreover, the elongated groove 244 helps to prevent relative movement between the locking clip 228 and the respective locking clip receiver assembly 254 on the frame 212 or forehead support 216, as will be further discussed below.

[0098] Figs. 29-34 show an embodiment of a frame 212 for a full-face mask assembly. The frame 212 may be permanently or removably connected to a cushion (not shown) in any suitable manner. Further, a swivel elbow assembly (not shown) may be removable attached to a front portion of the frame 212.

[0099] Each lateral side of the frame 212 includes a locking clip receiver assembly 254 structured to interlock with a locking clip 228. Similar to locking clip receiver assembly 54, the locking clip receiver assembly 254 includes a slot 256 having a central portion 258 and two locking portions 260. The locking portions 260 include a locking flange 270 (see Fig. 32) positioned on an outer wall thereof for engagement with the locking tab 238 of a locking clip 228. In the illustrated embodiment, an upper wall 261 of the slot 256 includes a pair of



openings 263 that are aligned with the locking flange 270. This enables the patient to visually confirm that the locking tab 238 of a locking clip 228 is interlocked with the locking flange 270 in use.

[00100] Also, the central portion 258 includes a wall 272. As best shown in Figs. 29, 30, and 32, the wall 272 provided in the locking clip receiver assembly 254 extends outwardly away from the slot 256. In the embodiment of locking clip receiver assembly 54, the wall 72 was positioned entirely within the slot 56 (see Figs. 5, 7, 11, and 12). The elongated wall 272 of locking clip receiver assembly 254 facilitates alignment of a clip 228 with a respective locking clip receiver assembly 254. Specifically, the groove 244 of a clip 228 may be engaged with the elongated wall 272 so as to guide the clip 228 into the slot 256.

[00101] Moreover, when a clip 228 is engaged with a respective locking clip receiver assembly 254, the engagement between the elongated groove 244 of the clip 228 and the wall 272 of the locking clip receiver assembly 254 prevents rocking or side-to-side movement between the clip 228 and locking clip receiver assembly 254. Further, any force applied to one of the spring arms 236 of the clip 228, when the clip 228 is engaged with the locking clip receiver assembly 254, will not be transferred to the other spring arm 236 of the clip 228. Thus, the clip 228 is prevented from being inadvertently disengaged from the respective locking clip receiver assembly 254 in use. To release the locking clip 228 from the locking clip receiver assembly 254, both spring arms 236 must be forced towards one another to clear the locking tabs 238 from respective locking flanges 270.

[00102] Figs. 35-40 show an embodiment of a forehead support 216 adapted to be movably mounted to an upper portion of the frame 212. The forehead support 216 may be provided with one or more fixed, permanent or removable forehead pads (not shown) in any suitable manner.

[00103] Each lateral side of the forehead support 216 includes a locking clip receiver assembly 254 structured to interlock with a locking clip 228. The locking clip receiver assembly 254 on the forehead support 216 is substantially similar to the locking clip receiver assembly on the frame 216 and indicated with similar reference numerals. As a result, one locking clip 228 can be used with the locking clip receiver assemblies 254 provided on the frame 212 and the forehead support 216, thereby reducing manufacturing costs and the need for inventory. Thus, four locking clips 228 are used, two locking clips 228 for the frame 212 and two locking clips 228 for the forehead support 216. In use, upper straps of a headgear assembly would be removably connected to the locking clips 228 for the forehead support 216

and lower straps of the headgear assembly would be removably connected to locking clips 228 for the frame 212.

**[00104]** Figs. 41-50 show additional embodiments of the present invention. Figs. 41-43 show a locking clip 300 which is similar to the locking clip 228 shown in Figs. 21-23. The locking clip 300 is constructed and arranged for use with a nasal or full face mask having a locking clip receiving assembly and provided with headgear, as described above. However, locking clip 300 includes raised finger grip portions 302 which are larger than the grip portions shown, e.g., in Fig. 22. Each grip portion may include one or more grooves 303. The enlarged finger grip portions 302 shown in Figs. 41-43 offer a larger grip for the fingers since they protrude and therefore allow the clip to be more easily squeezed upon assembly and disassembly. Furthermore, the larger finger grip surfaces help to reduce user discomfort (sore fingers) when squeezing the clip. Figs. 44-46 show yet another embodiment, similar to the embodiment of Figs. 41-43, in which a locking clip 304 includes finger grip portions 306 and grooves 307 which are even larger than the finger grip portions 302 and grooves 303 shown in Figs. 41-43. The enlarged finger grip portions shown in Figs. 44-46 also enable easier assembly and disassembly. The finger grip portions 306 offer a larger grip for the fingers since they protrude and therefore allow the clip to be more easily squeezed upon disassembly. As an example, grip portions 302 may protrude about 1-3 mm away from flexing arms, while grip portions 306 may extend from 2-6 mm away from flexing arms.

**[00105]** Figs. 47-49 illustrate yet another embodiment of the present invention. Locking clip 310 includes a modified body and arm design. Locking clip includes a pair of flexible spring arms 312. Each arm 312 includes a first end 314 including a locking tab 316 and a second end 318, near front portion 319 of clip 304, attached to the main body 320. Each arm 312 is spaced from the main body 320 by a flexing space 322. Arm 312 includes a central portion 324 that is angled with respect to proximal portion 326 of arm 312. Central portion 324 is spaced by a gap 328 from rear portion 330. Gaps 322 and 328 may form the general shape of the letter "L." The design of the arms 312 in this manner, e.g., a spring loop, allows for effective compact lengthening of the arms so as to reduce the force required to squeeze clip upon assembly and/or disassembly. This reduced force may also provide the user with a softer and/or improved feel, since the looped design allows the arm to deflect about a greater effective length, without sacrificing spring/clip retention forces.

**[00106]** Figs. 47-49 include finger grip portions like those shown in Figs. 21-28, but the finger grip portions shown in Figs. 41-46 could also be used. Fig. 50 is a side view of clip

310. Figs. 47-50 include exemplary dimensions of clip 310. However, the dimensional values can be changed to suit the particular application. In embodiments, the dimensions can be changed to be up to  $\pm 20\%$ , and preferably up to  $\pm 10\%$ , of the values shown.

[00107] The clip 310 may be made of a polyester material, e.g., POCAN B1501, although other materials are possible.

[00108] It can thus be appreciated that the aspects of the present invention have been fully and effectively accomplished. The foregoing specific embodiments have been provided to illustrate the structural and functional principles of the present invention, and are not intended to be limiting. To the contrary, the present invention is intended to encompass all modifications, alterations and substitutions within the spirit and scope of the detailed description.

WHAT IS CLAIMED IS:

1. A respiratory mask assembly for delivering breathable gas to a patient, comprising:
  - a frame having a main body and a side frame member provided on each lateral side of the main body, at least one of the side frame members including an integrally formed locking clip receiver assembly; and
  - at least one locking clip having a main body providing a front portion and a rear portion, the front portion adapted to be removably coupled with the at least one locking clip receiver assembly and the rear portion adapted to be removably coupled to a headgear assembly,
  - wherein the rear portion of the locking clip includes a cross bar that forms an opening through which a strap of the headgear assembly can pass and be removably coupled with the cross bar, and the front portion of the locking clip includes at least one resiliently flexible spring arm that is flexible within the plane of the main body.
2. A respiratory mask assembly according to claim 1, wherein the locking clip receiver assembly includes a slot and the spring arm includes a locking tab at a free end thereof, the locking tab configured to be inserted into the slot and interlocked with the locking flange provided within the slot to removably couple the locking clip to the locking clip receiver assembly.
3. A respiratory mask assembly according to claim 1, wherein the locking clip receiver assembly includes a slot and the locking clip includes a central support tab that is inserted into the slot when the locking clip and locking clip receiver assembly are removably coupled so as to prevent relative movement between the locking clip and the locking clip receiver assembly.
4. A respiratory mask assembly according to claim 3, wherein the locking clip includes a pair of spring arms, the central support tab being positioned between the pair of spring arms and having a length that is greater than a length of each of the spring arms.
5. A respiratory mask assembly according to claim 4, wherein the slot includes a locking portion and a central portion, the at least one spring arm being insertable into the

locking portion of the slot and the central support tab being insertable into the central portion of the slot.

6. A respiratory mask assembly according to claim 5, wherein the locking portion of the slot has a height approximately equal to a height of a front portion of the at least one spring arm, and the central portion of the slot has a height approximately equal to a height of the central support tab.

7. A respiratory mask assembly according to claim 6, wherein the height of the locking portion is less than the height of the central portion to prevent the central support tab from being inserted into the locking portion of the slot.

8. A respiratory mask assembly according to claim 4, wherein the slot includes a protrusion and the central support tab includes a groove, the protrusion being inserted into the groove when the locking clip and locking clip receiver assembly are removably coupled to one another.

9. A respiratory mask assembly according to claim 8, wherein the protrusion extends outwardly away from the slot.

10. A respiratory mask assembly according to claim 8, wherein the groove has a length that is at least half a length of the central support tab.

11. A respiratory mask assembly according to claim 8, wherein a force applied to one of the pair of spring arms is not be transferred to the other of the pair of spring arms due to the engagement between the groove of the central support tab and the protrusion of the slot.

12. A respiratory mask assembly according to claim 1, wherein the locking clip is configured to allow the patient to grasp the same between the thumb and forefinger of the patient.

13. A respiratory mask assembly according to claim 1, wherein both side frame members include a locking clip receiver assembly, and the mask assembly includes a pair of

locking clips adapted to be removably coupled with a respective one of the locking clip receiver assemblies.

14. A respiratory mask assembly according to claim 1, wherein the mask assembly is a nasal mask.

15. A locking clip for removably coupling a frame and a headgear assembly of a respiratory mask assembly for delivering breathable gas to a patient, the locking clip comprising:

a main body providing a front portion and a rear portion, the front portion adapted to be removably coupled with the frame and the rear portion adapted to be removably coupled to the headgear assembly,

wherein the rear portion includes a cross bar that forms an opening through which a strap of the headgear assembly can pass and be removably coupled with the cross bar, and the front portion includes at least one resiliently flexible spring arm that is flexible within the plane of the main body.

16. The locking clip according to claim 15, wherein the spring arm includes a locking tab at a free end thereof, the locking tab configured to be inserted into a slot of the frame and interlocked with a locking flange provided within the slot to removably couple the locking clip to the frame.

17. The locking clip according to claim 15, wherein the locking clip includes a central support tab that is inserted into a slot of the frame when the locking clip and frame are removably coupled so as to prevent relative movement between the locking clip and the frame.

18. The locking clip according to claim 17, wherein the locking clip includes a pair of spring arms, the central support tab being positioned between the pair of spring arms and having a length that is greater than a length of each of the spring arms.

19. The locking clip according to claim 18, wherein the central support tab includes a groove that receives a protrusion provided in the slot when the locking clip and frame are removably coupled to one another.

20. The locking clip according to claim 19, wherein the groove has a length that is at least half a length of the central support tab.

21. The locking clip according to claim 19, wherein a force applied to one of the pair of spring arms is not be transferred to the other of the pair of spring arms due to the engagement between the groove of the central support tab and the protrusion of the slot.

22. The locking clip according to claim 17, wherein the central support tab has a height that is greater than a height of a front portion of the at least one spring arm.

23. The locking clip according to claim 15, wherein the locking clip is configured to allow the patient to grasp the same between the thumb and forefinger of the patient.

24. A respiratory mask assembly for delivering breathable gas to a patient, comprising:

a frame having a main body and a side frame member provided on each lateral side of the main body, at least one of the side frame members including an integrally formed locking clip receiver assembly; and

at least one locking clip having a main body providing a front portion and a rear portion, the front portion adapted to be removably coupled with the at least one locking clip receiver assembly and the rear portion adapted to be removably coupled to a headgear assembly,

wherein the front portion and rear portion of the at least one locking clip are disposed at an angle with respect to one another.

25. A respiratory mask assembly according to claim 24, wherein the front portion is generally aligned with the at least one locking clip receiver assembly when the front portion is removably coupled with the at least one locking clip receiver assembly and the rear portion is angled with respect to the front portion such that the rear portion extends towards the patient's face when the mask assembly is secured to the patient's face.

26. A respiratory mask assembly according to claim 24, wherein the rear portion of the locking clip includes a cross bar that forms an opening through which a strap of the headgear assembly can pass and be removably coupled with the cross bar, and the front portion of the locking clip includes at least one resiliently flexible spring arm that is flexible within the plane of the main body.

27. A respiratory mask assembly for delivering breathable gas to a patient, comprising:

a frame having a main body and a side frame member provided on each lateral side of the main body,

the main body providing an orifice therethrough for the introduction of breathable gas into a nasal breathing cavity and a collar that substantially surrounds the orifice,

at least one of the side frame members including an integrally formed locking clip receiver assembly,

wherein the frame is formed by molding such that mold components of a mold can be withdrawn along a single plane to separate the mold from the collar and the locking clip receiver assembly.

28. A respiratory mask assembly according to claim 27, further comprising an elbow assembly coupled to the collar.

29. A respiratory mask assembly according to claim 27, further comprising at least one locking clip having a main body providing a front portion and a rear portion, the front portion adapted to be removably coupled with the at least one locking clip receiver assembly and the rear portion adapted to be removably coupled to a headgear assembly.

30. A respiratory mask assembly according to claim 29, wherein the rear portion of the locking clip includes a cross bar that forms an opening through which a strap of the headgear assembly can pass and be removably coupled with the cross bar, and the front portion of the locking clip includes at least one resiliently flexible spring arm that is flexible within the plane of the main body.



31. A method for molding a frame for a respiratory mask assembly, the method comprising:

molding a frame in a mold to include a main body and a side frame member provided on each lateral side of the main body, the main body defining an orifice therethrough and a collar that substantially surrounds the orifice;

forming at least one locking clip receiver assembly on at least one of the side frame members; and

withdrawing opposed mold components of the mold along a single plane to separate the mold from the collar and the locking clip receiver assembly.

#### ABSTRACT OF THE DISCLOSURE

A respiratory mask assembly for delivering breathable gas to a patient includes a frame and at least one locking clip. The frame has a main body and a side frame member provided on each lateral side of the main body, at least one of the side frame members including a locking clip receiver assembly. The at least one locking clip has a main body providing a front portion adapted to be removably coupled with the at least one locking clip receiver assembly and a rear portion adapted to be removably coupled to a headgear assembly. The rear portion includes a cross bar that forms an opening through which a strap of the headgear assembly can pass and be removably coupled with the cross bar, and the front portion includes at least one resiliently flexible spring arm that is flexible within the plane of the main body.

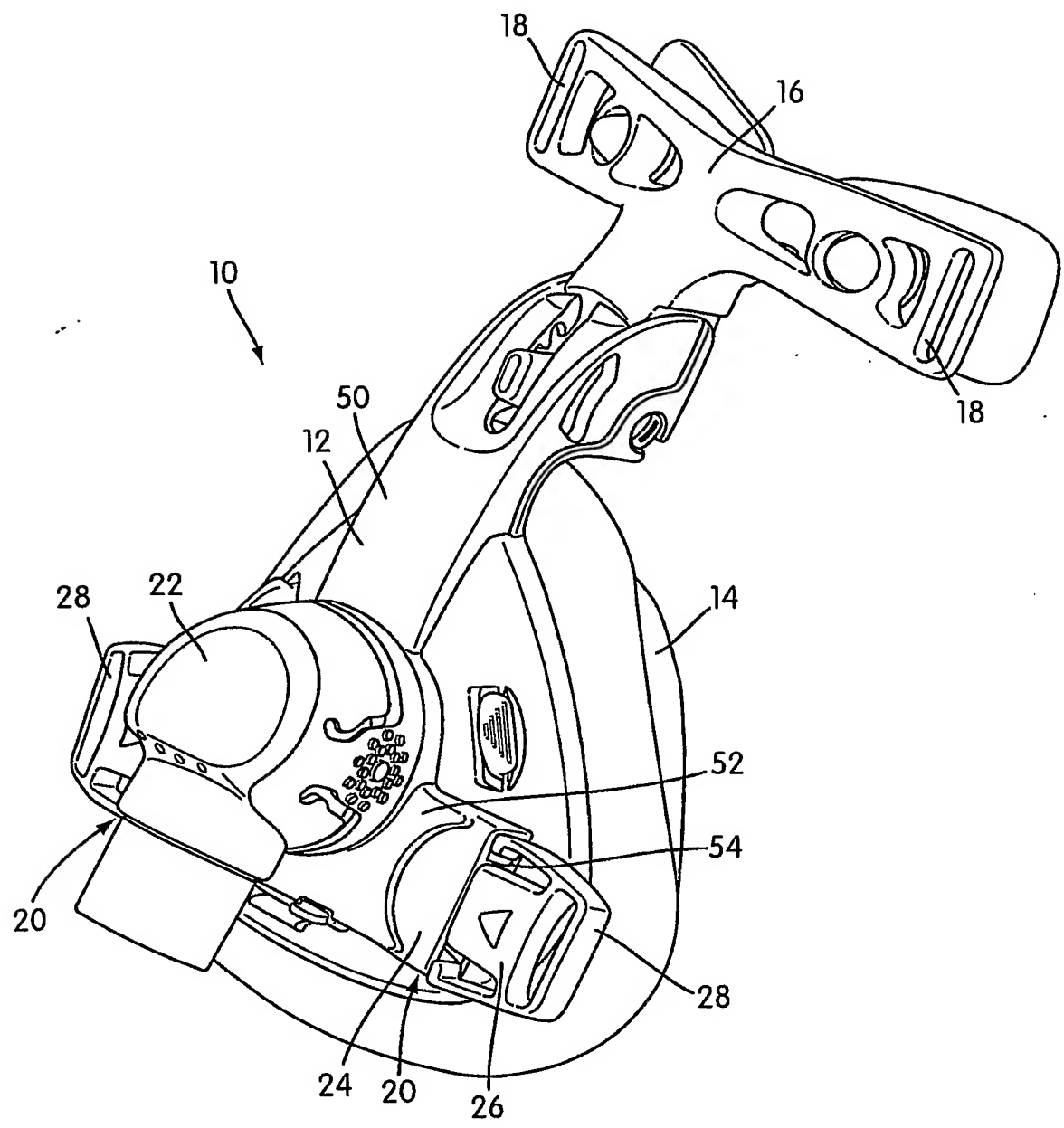


FIG. 1

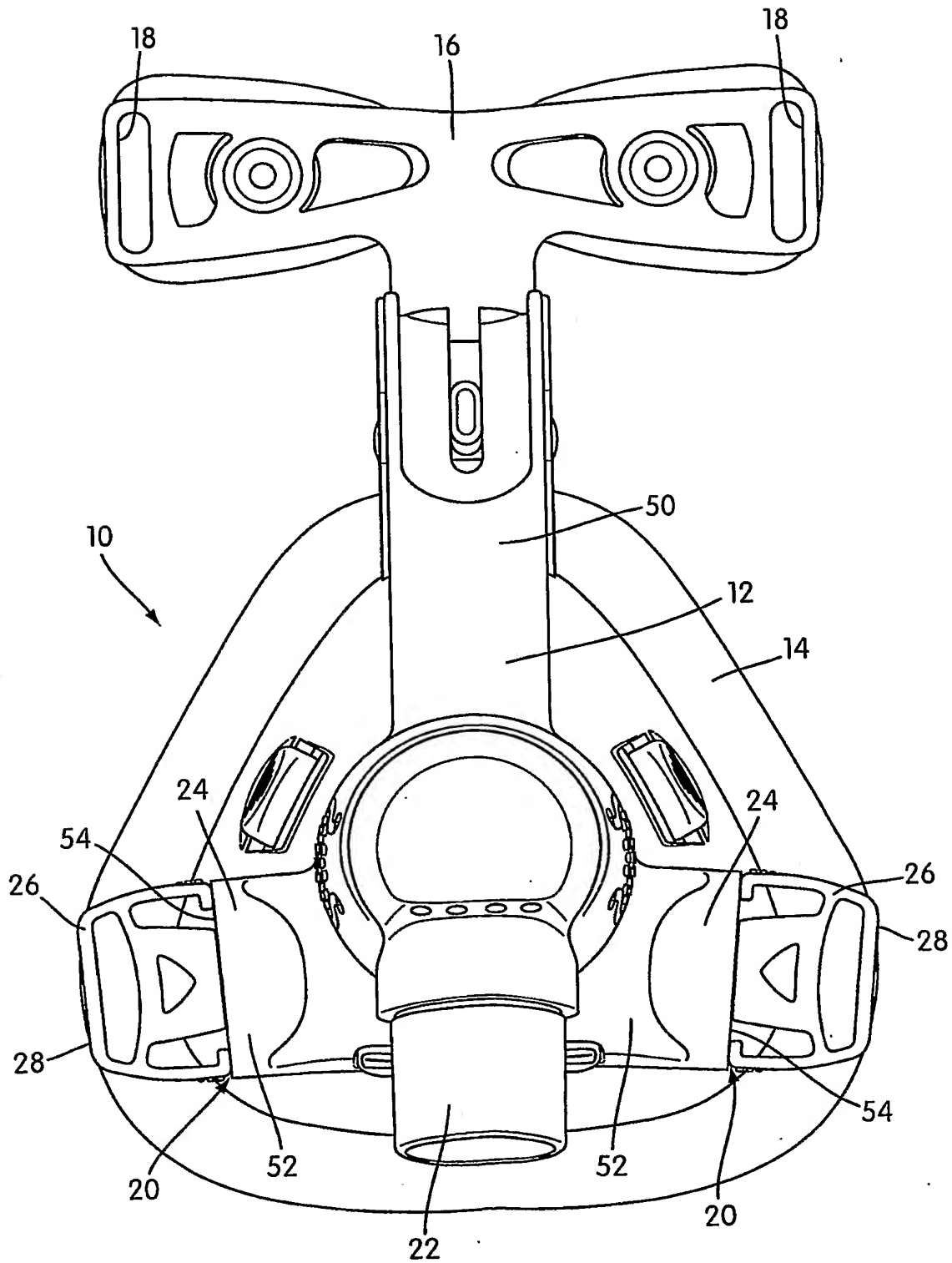


FIG. 2

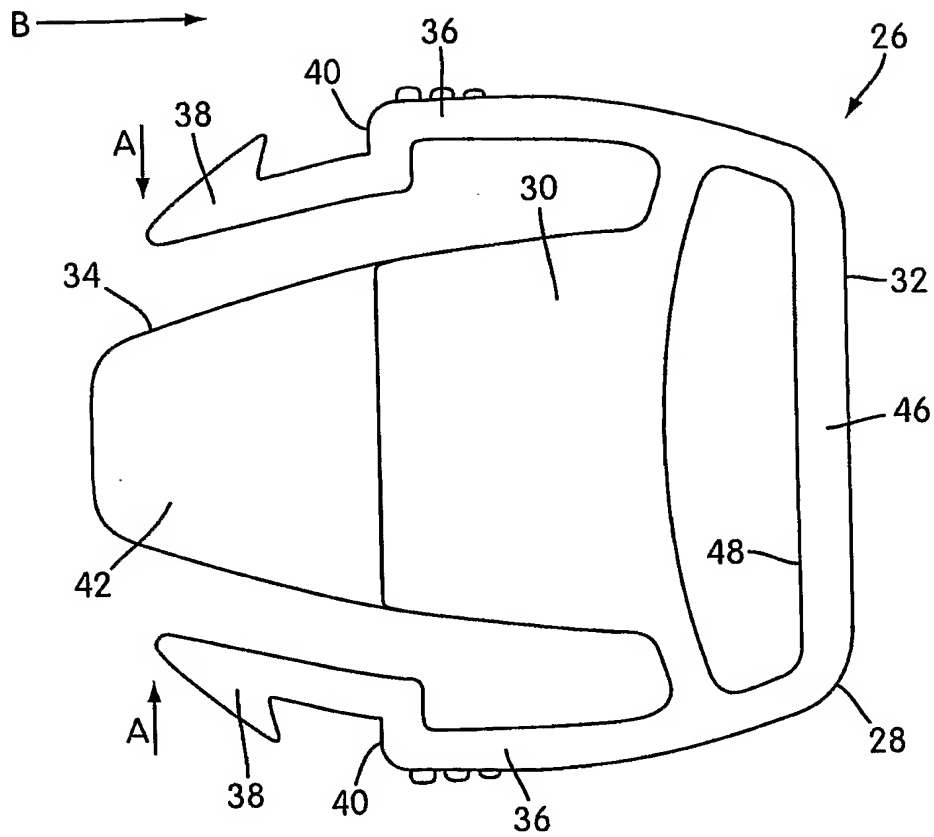


FIG. 3

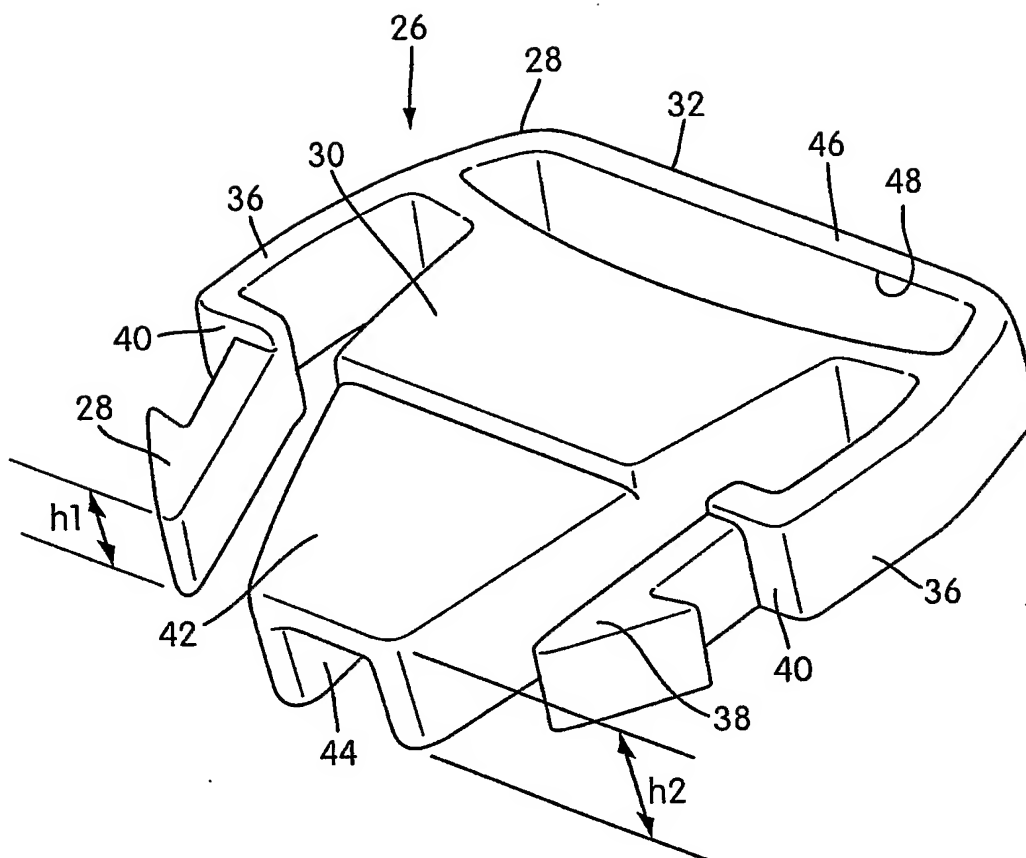


FIG. 4

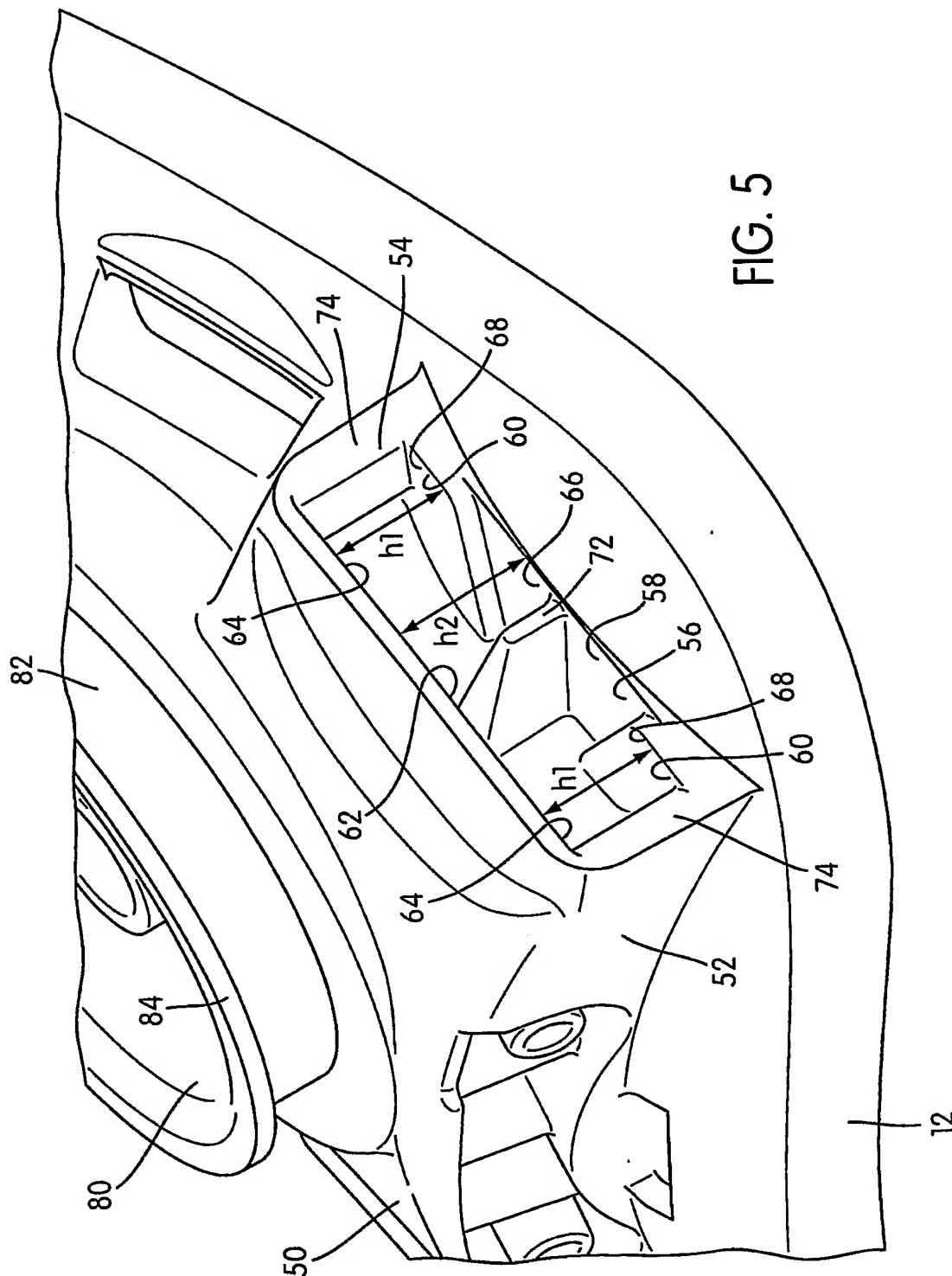


FIG. 5

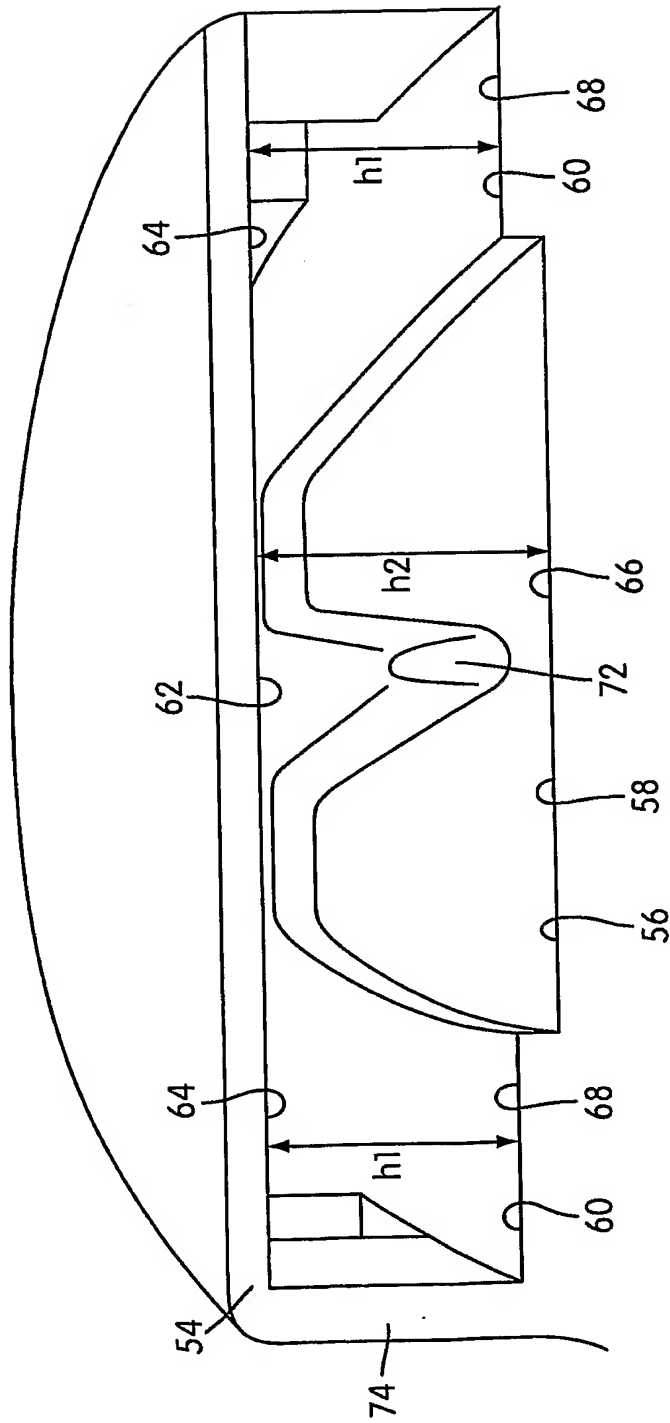


FIG. 6



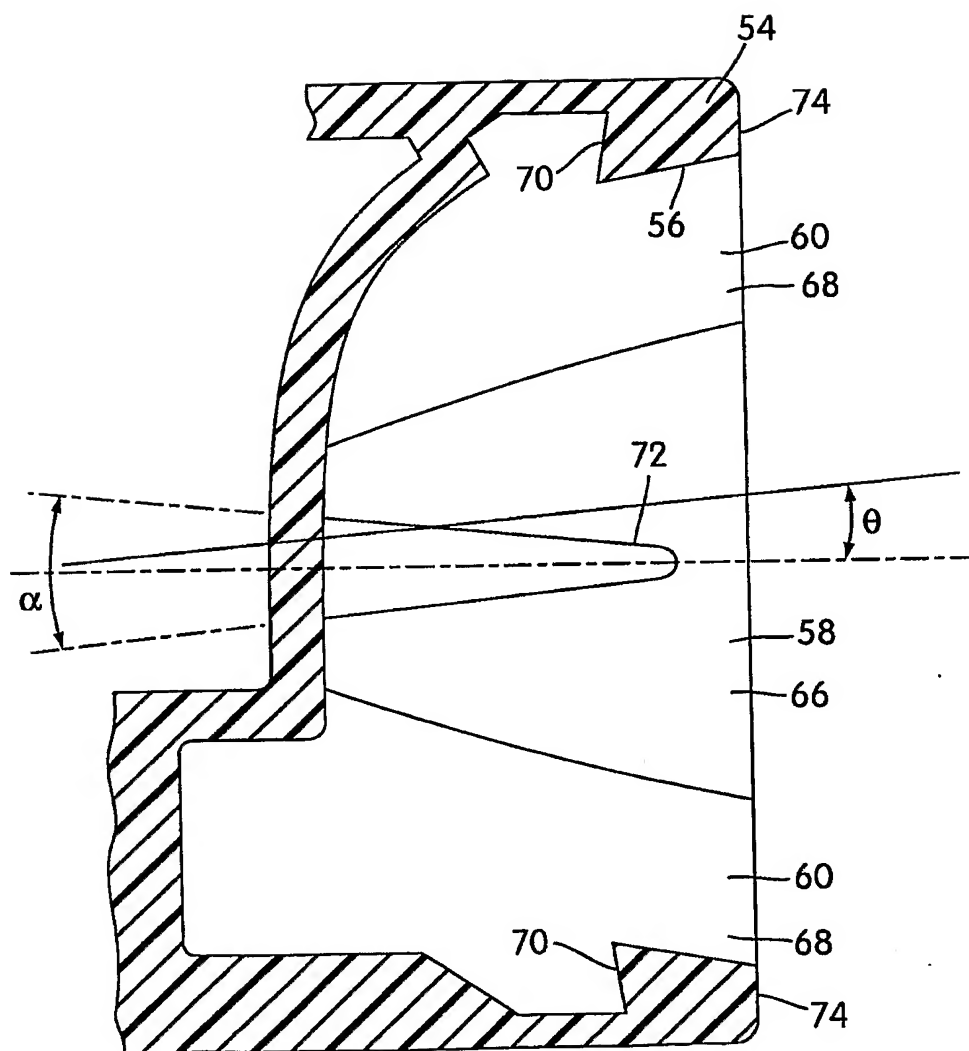


FIG. 7

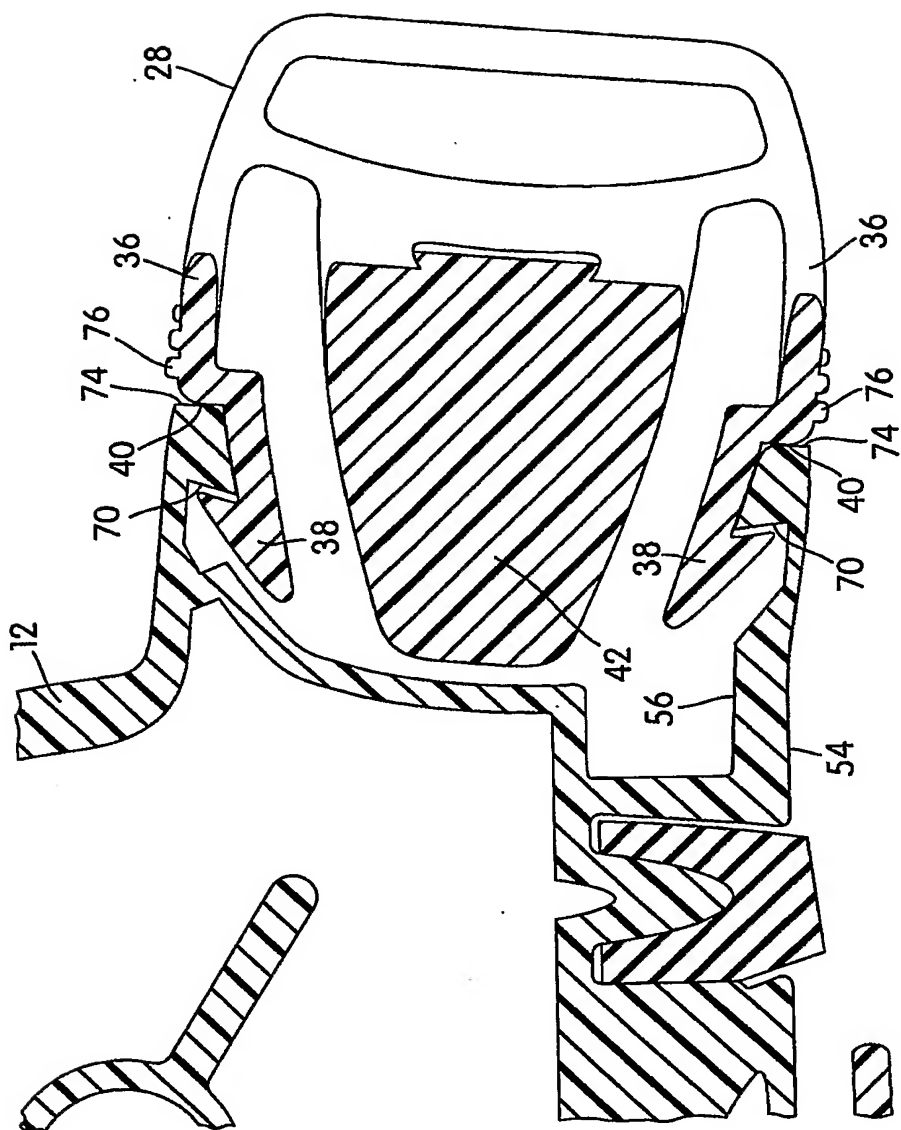


FIG. 8

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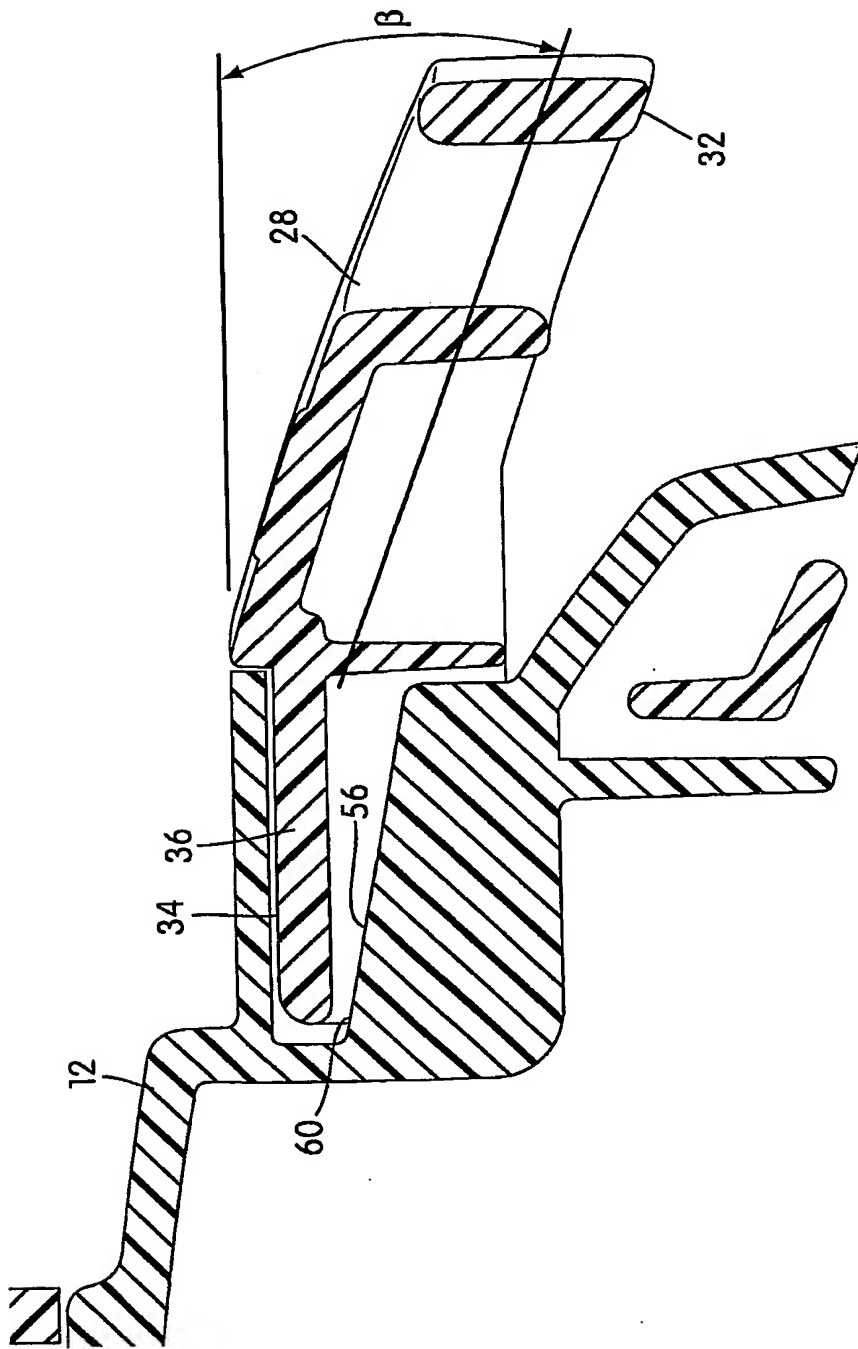


FIG. 9

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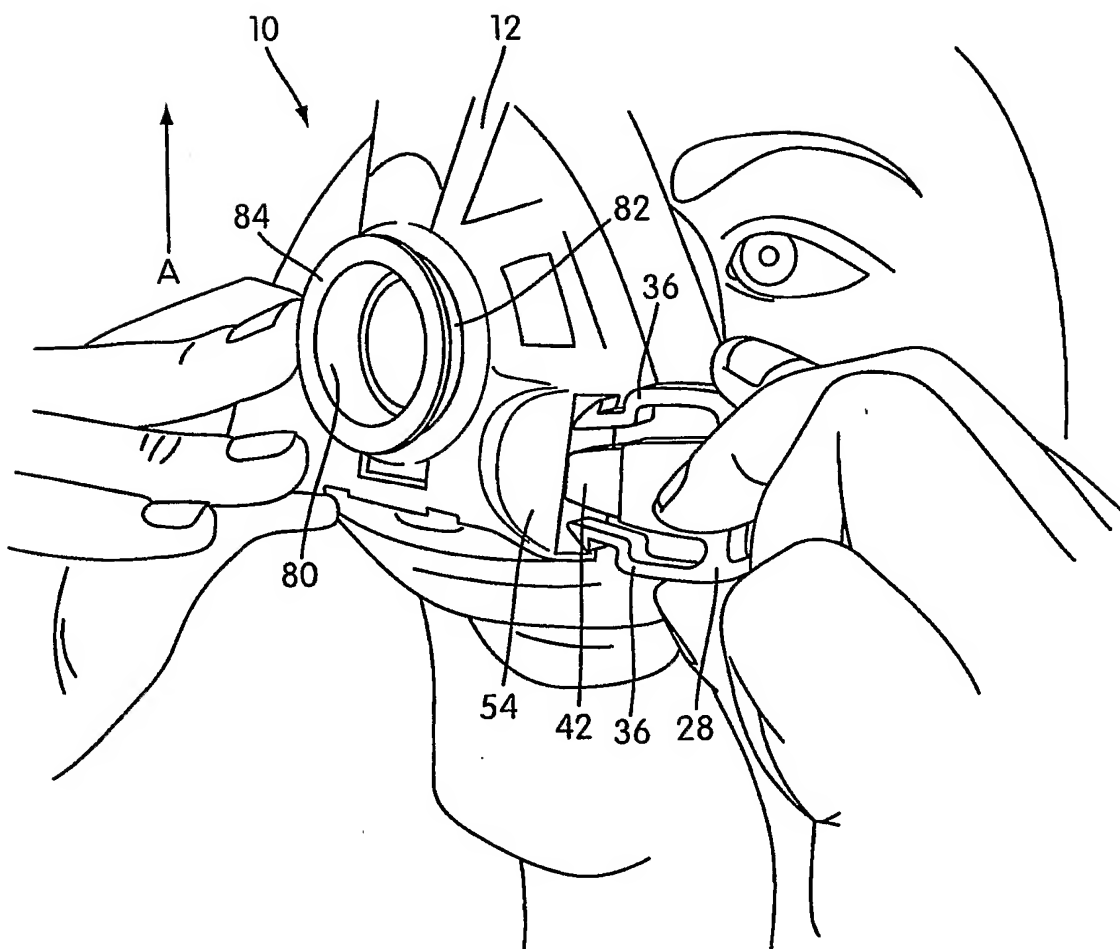
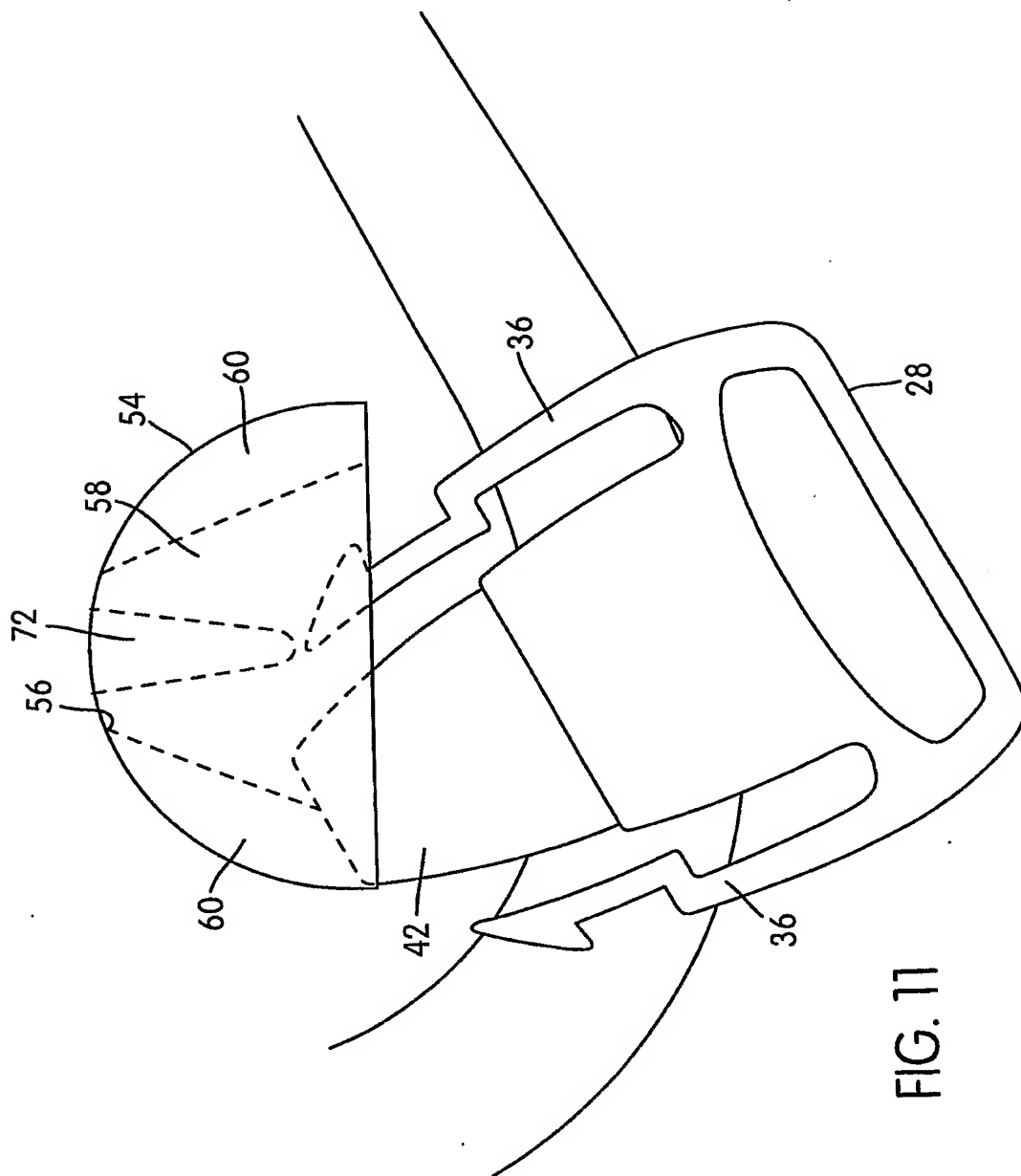


FIG. 10

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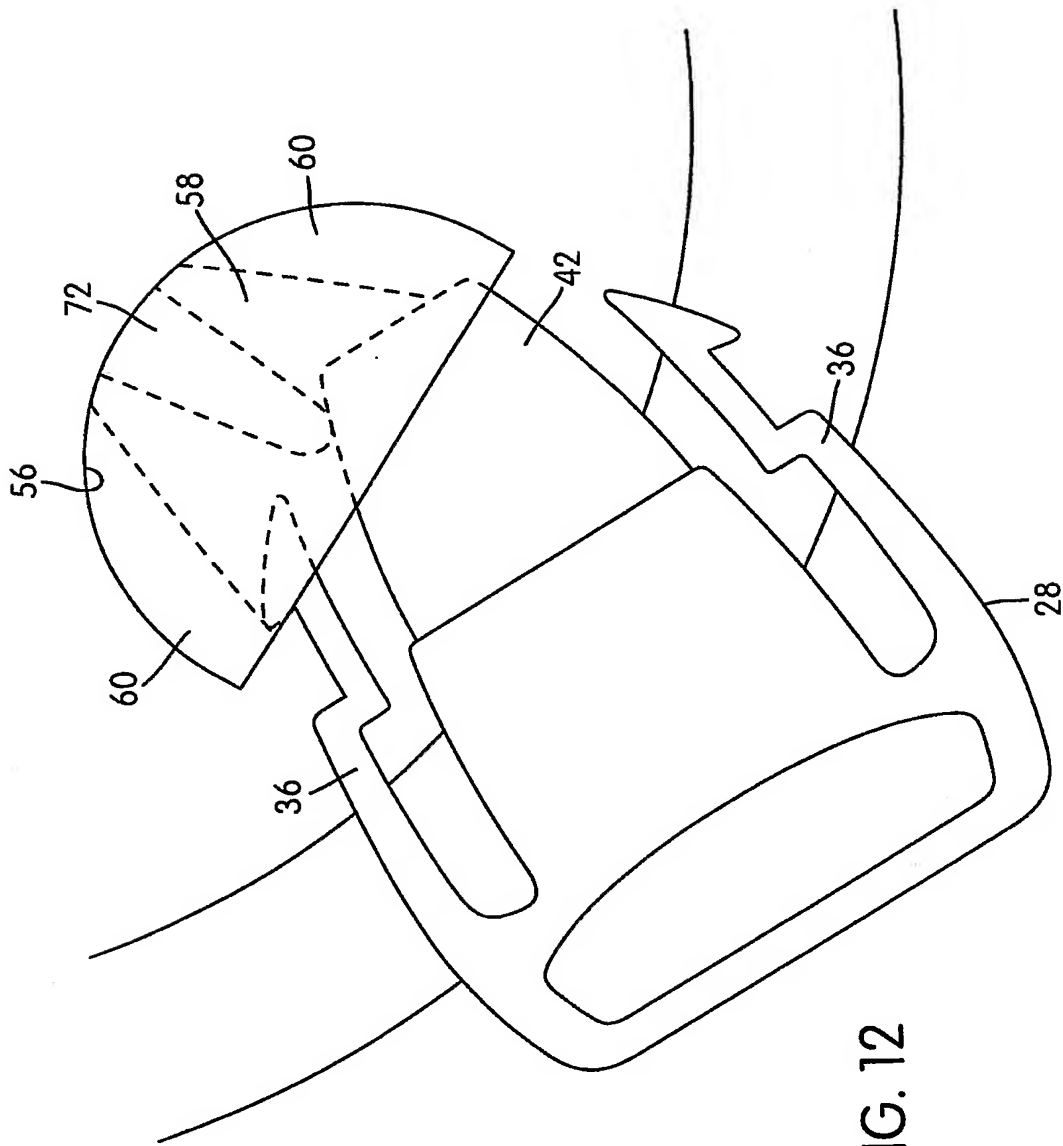


FIG. 12

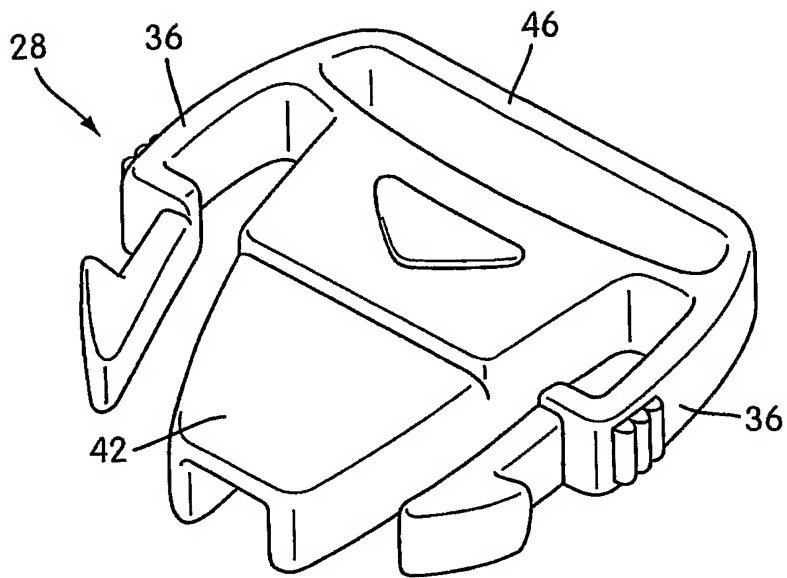


FIG. 13

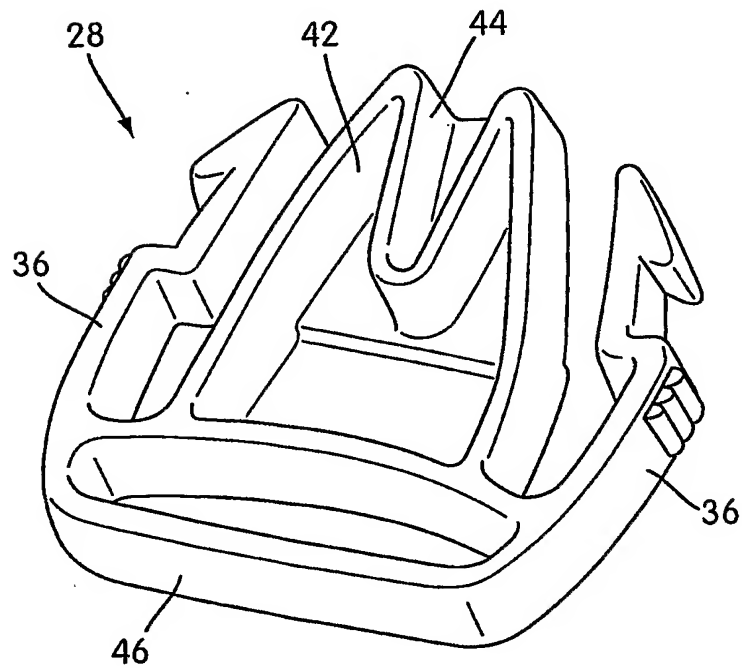
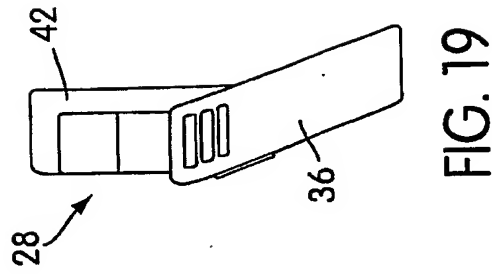
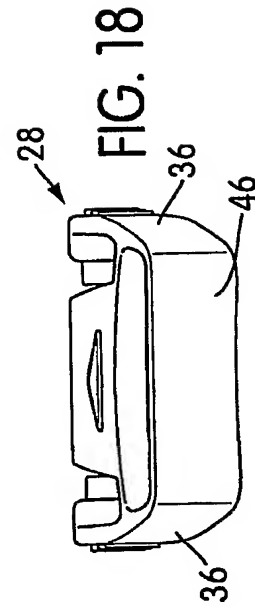
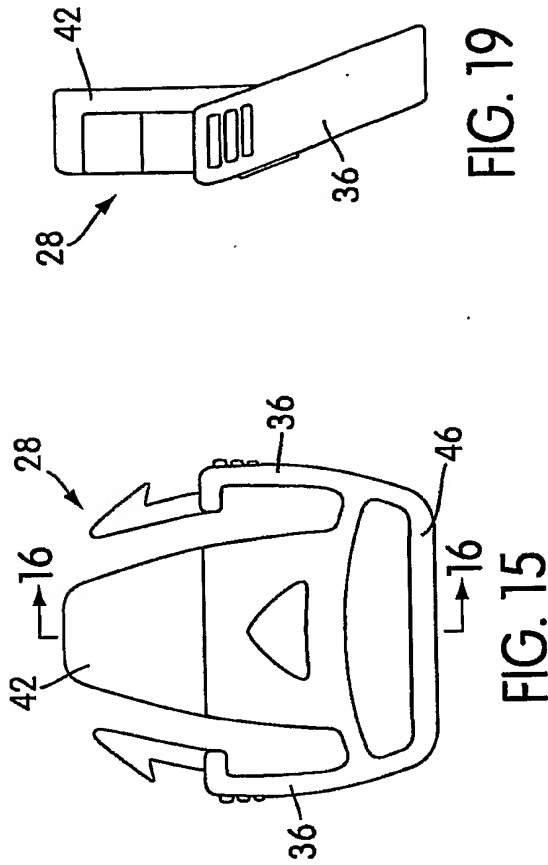
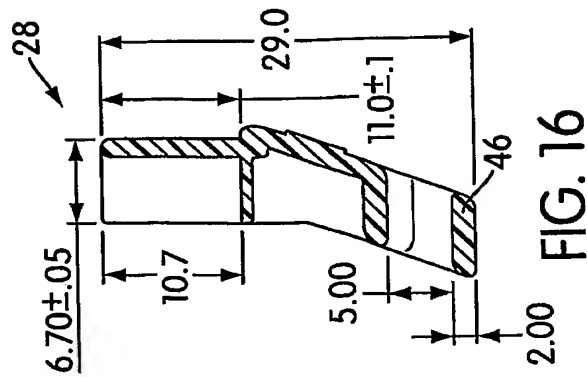
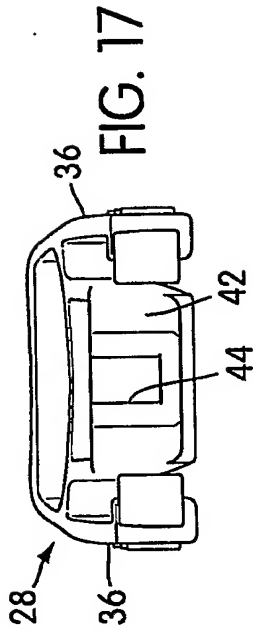


FIG. 14





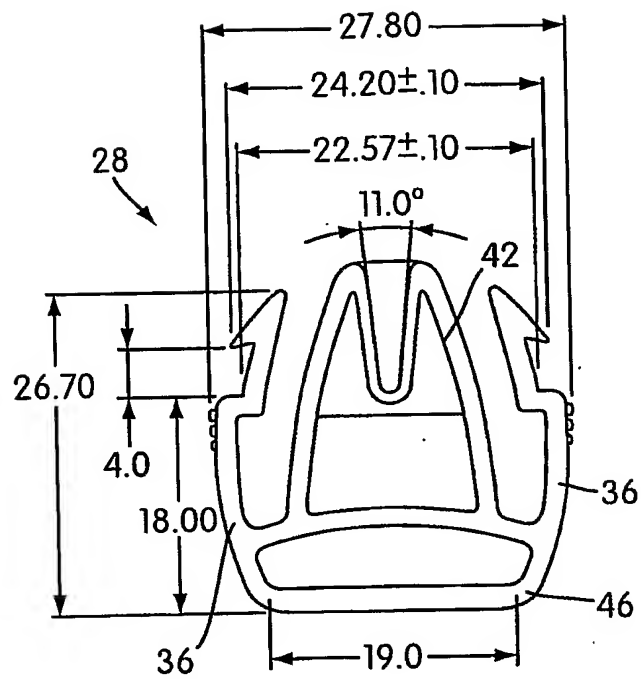


FIG. 20

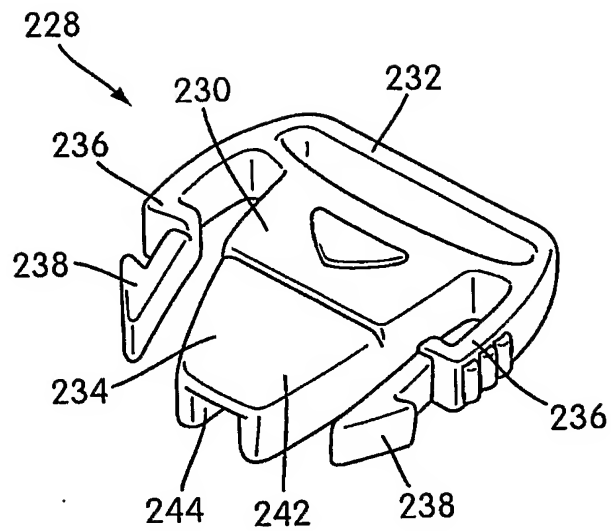


FIG. 21

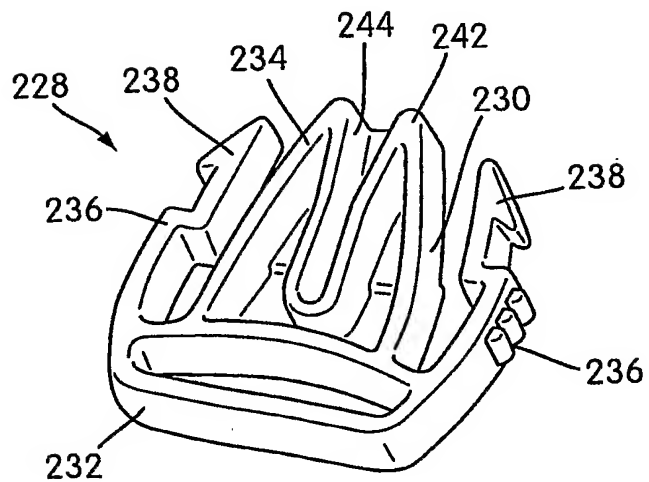


FIG. 22

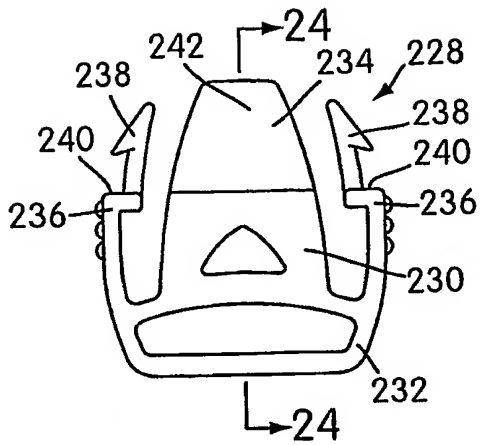


FIG. 23

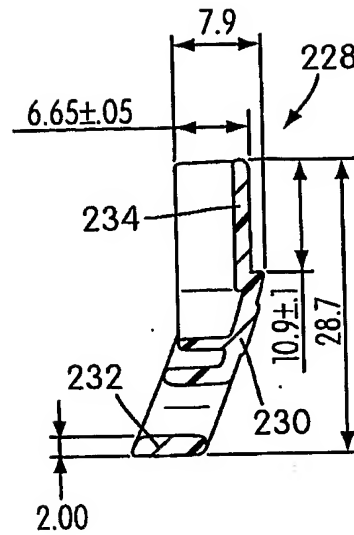


FIG. 24

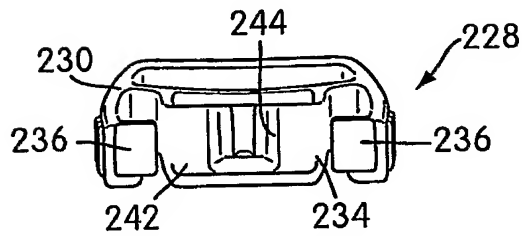


FIG. 25

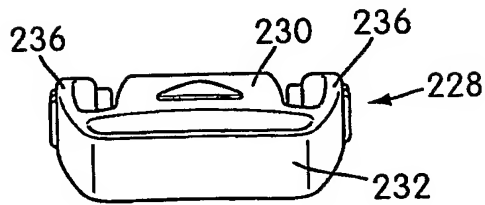


FIG. 26

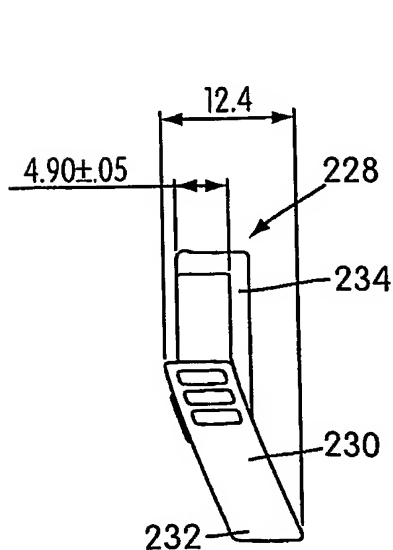


FIG. 27

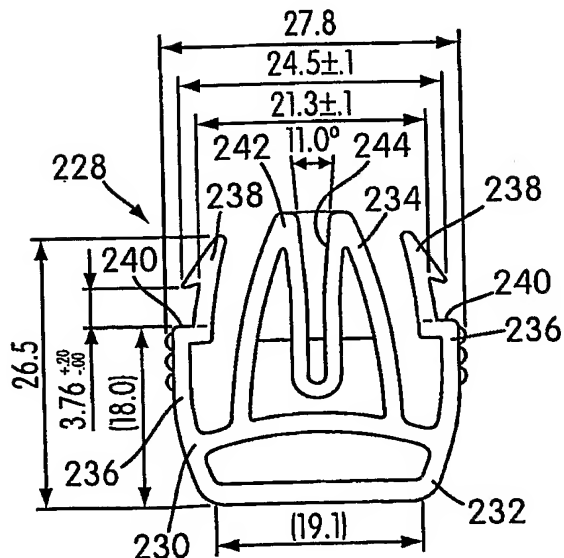


FIG. 28

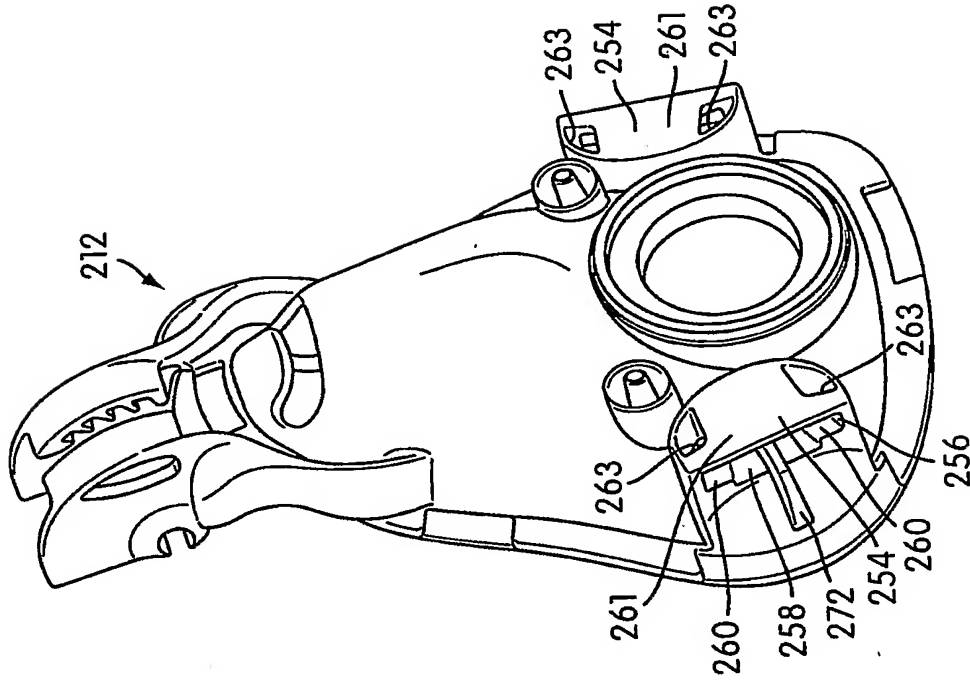


FIG. 30

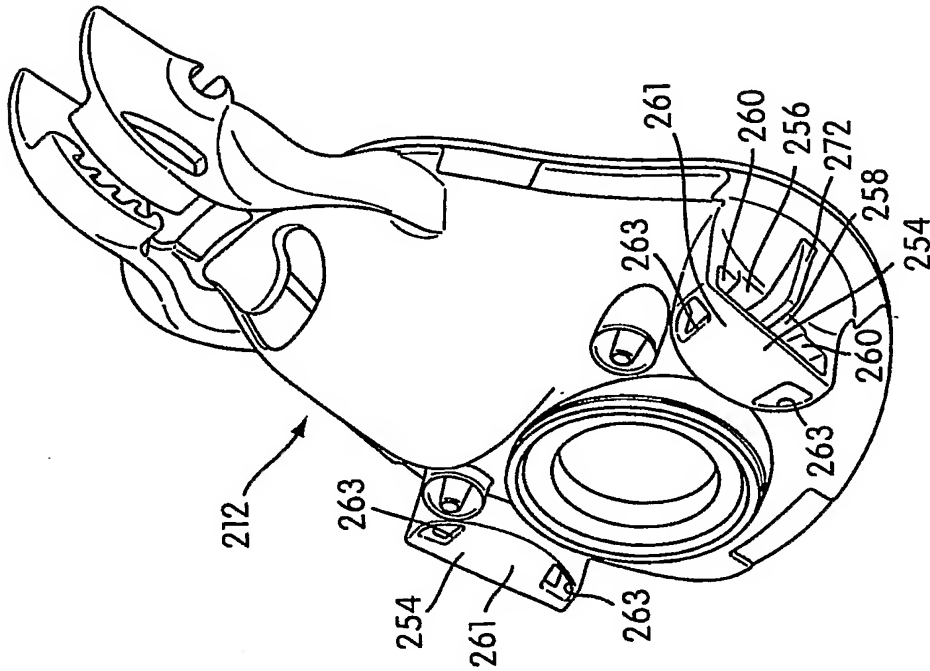


FIG. 29

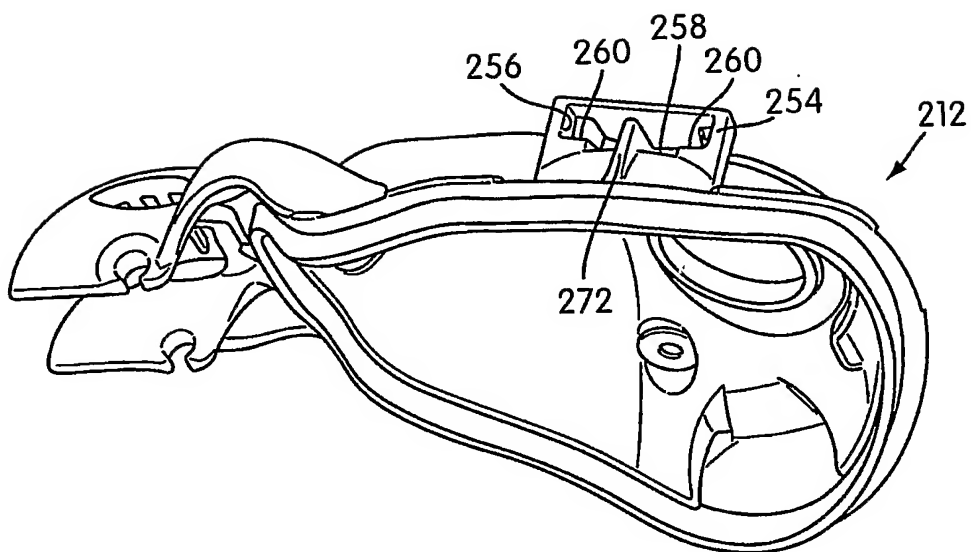


FIG. 31

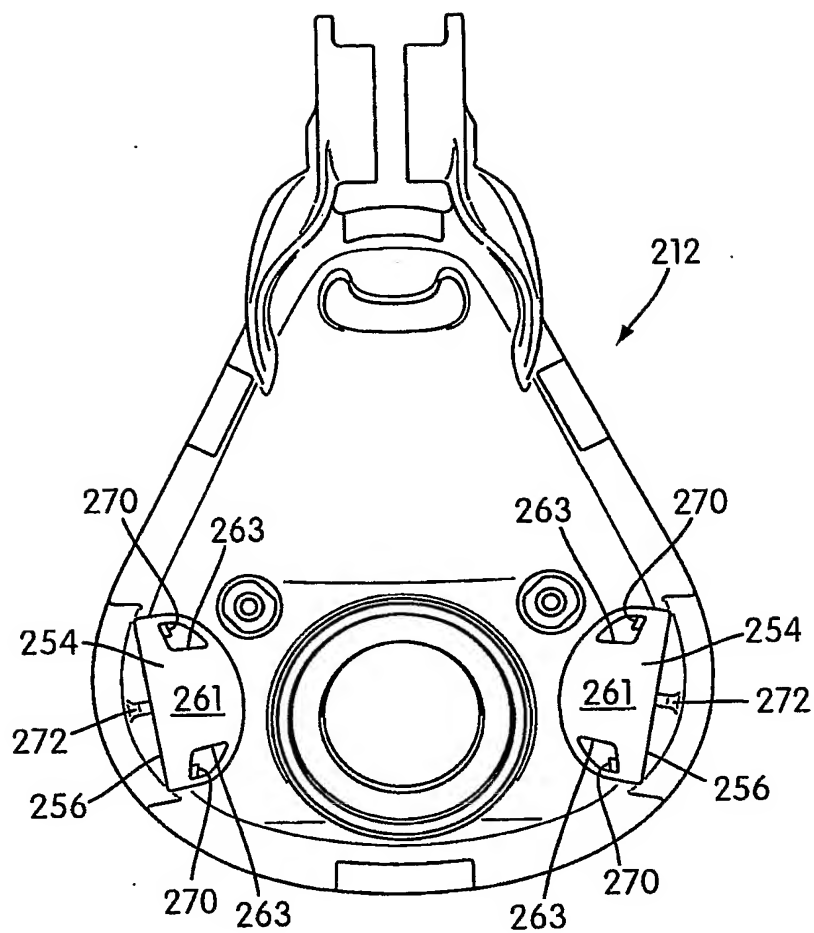


FIG. 32

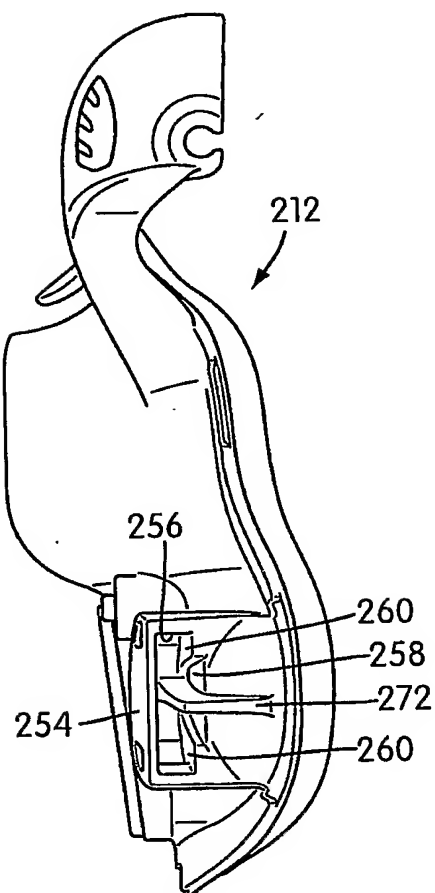


FIG. 33

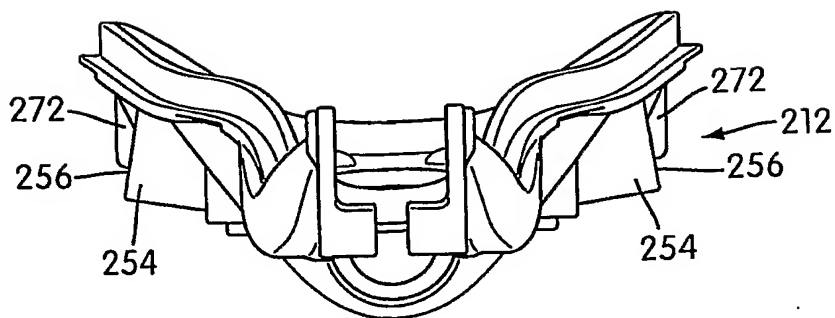


FIG. 34

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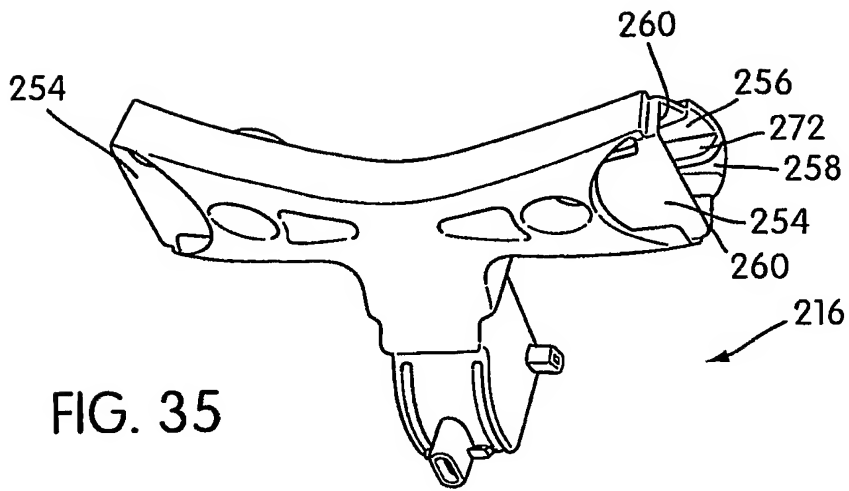


FIG. 35

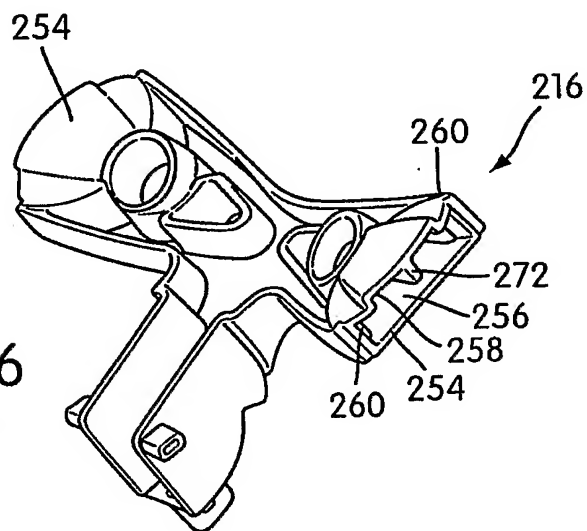


FIG. 36

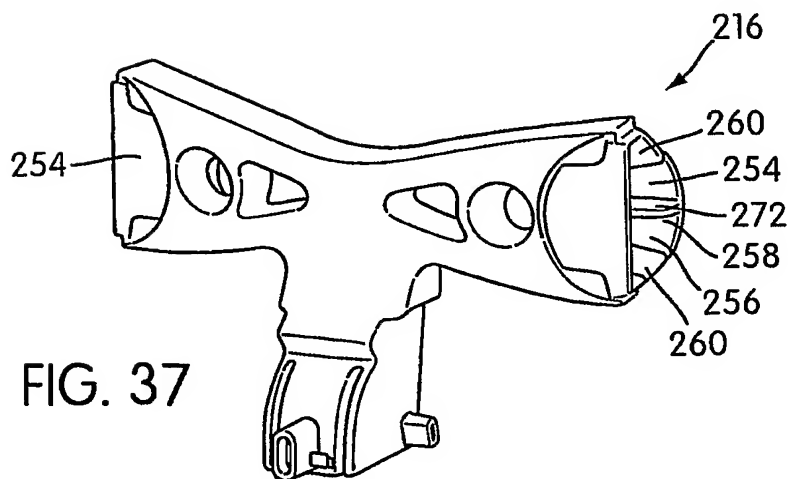
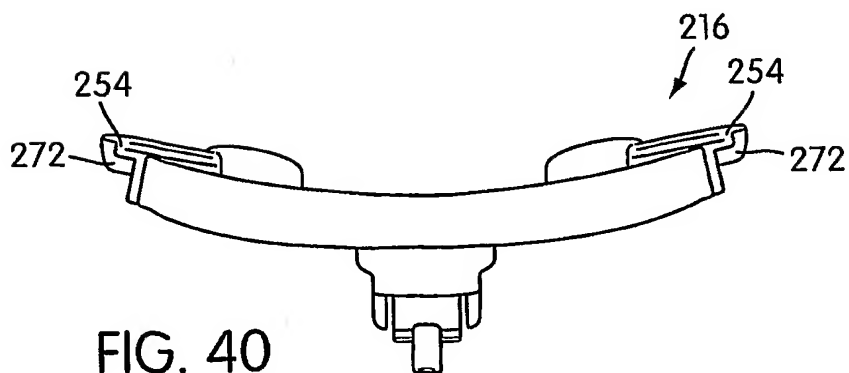
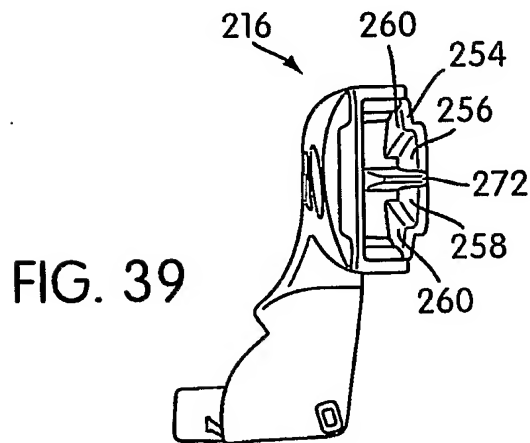
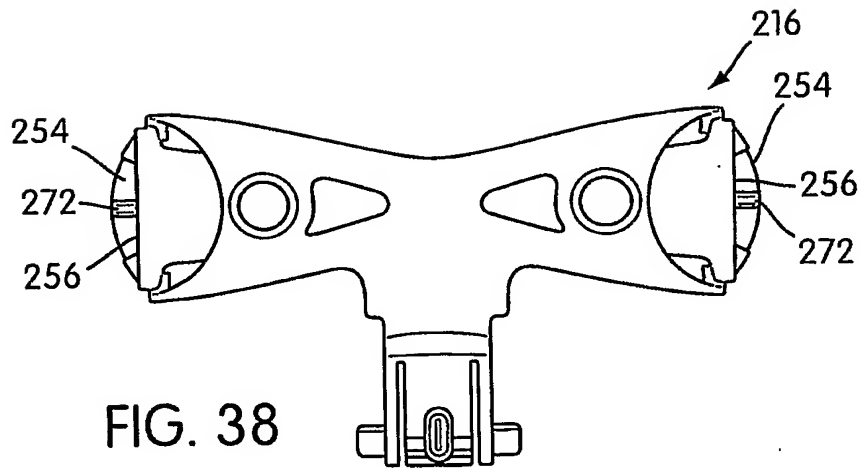


FIG. 37



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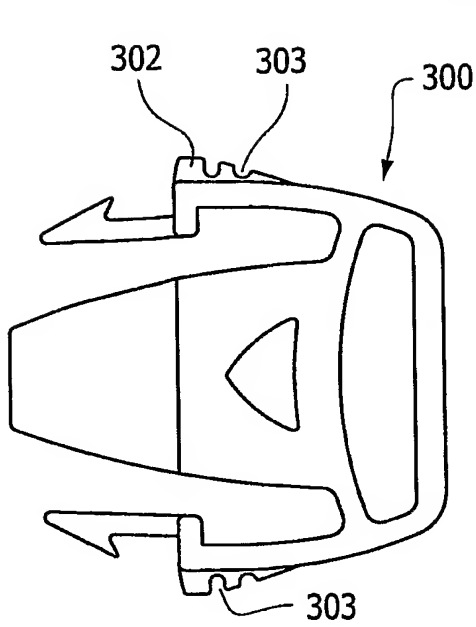


FIG. 41

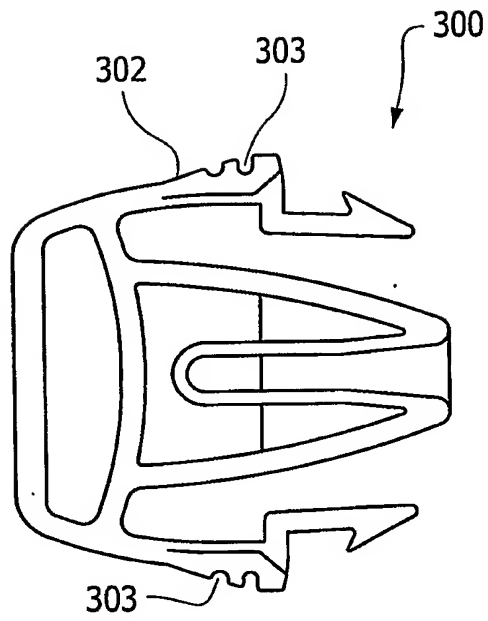


FIG. 42

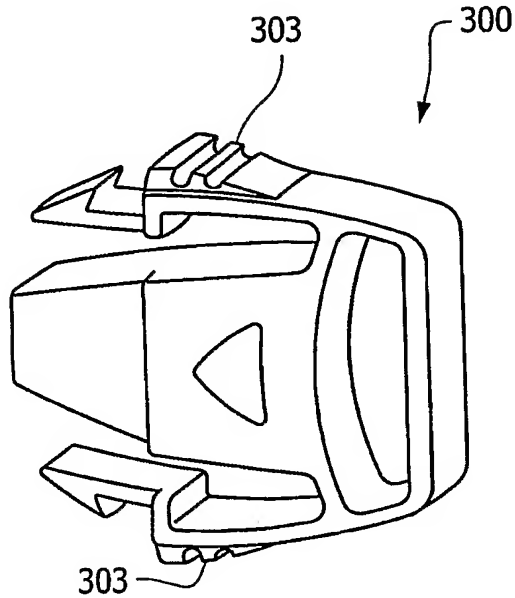


FIG. 43

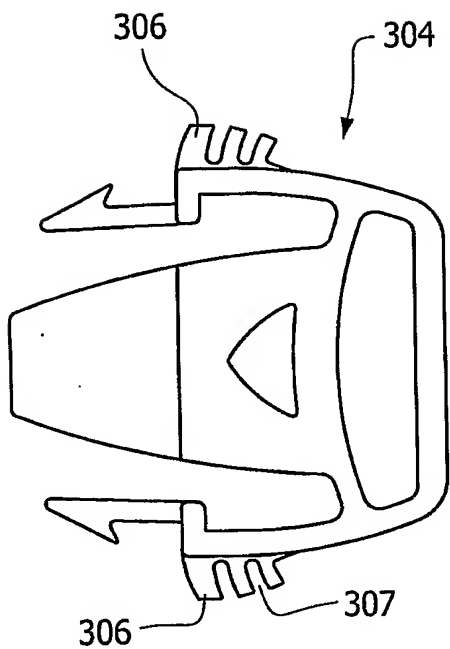


FIG. 44

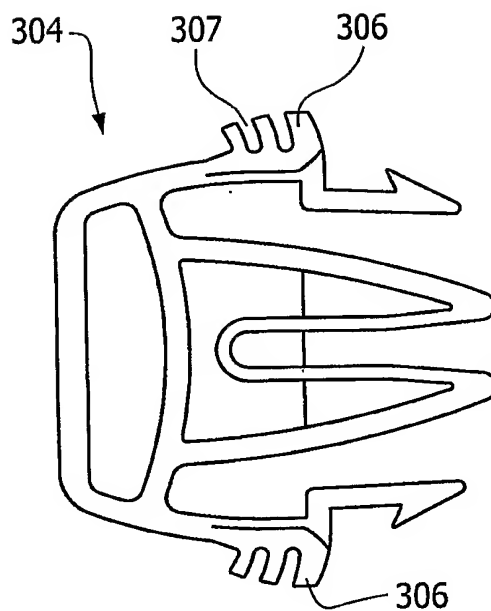


FIG. 45

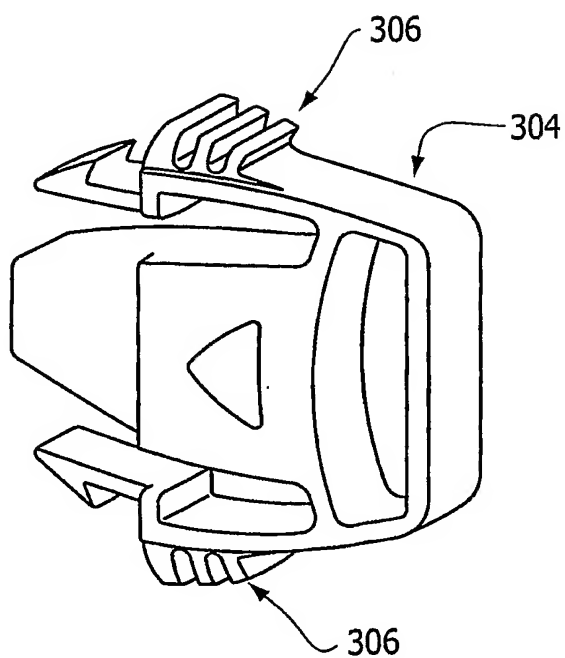


FIG. 46

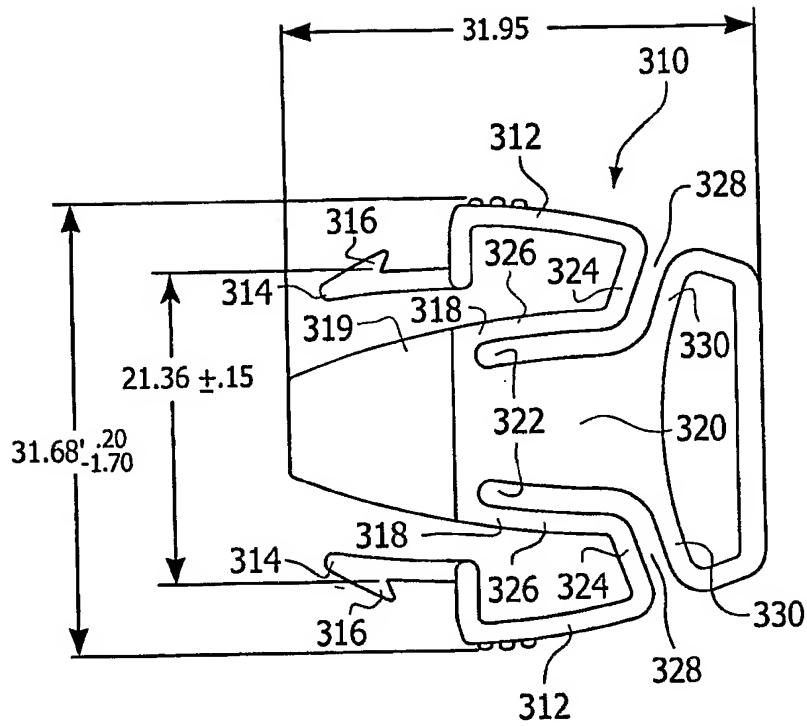


FIG. 47

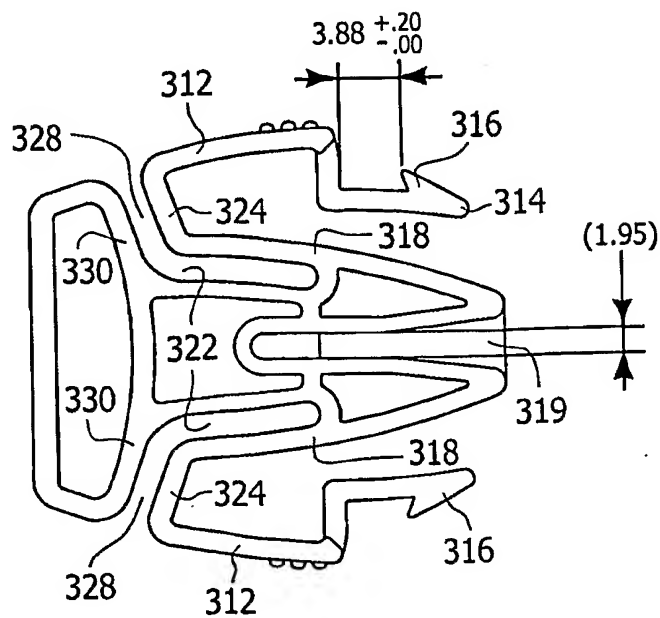


FIG. 48

